

US3372284 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:16:42

All time stamps listed in this document are displayed in GMT

US3372284

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:47:17

Generated On: 09 Jun 2021 17:16:42

[Participant ID](#)

US3372284

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

US3372284

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:17:01

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 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) 16 Feb 2021 23:10:43

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1965 |
| Age | 55 |
| Age Units | YEARS |
| Age (Derived) | 55 |
| 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 |

US3372284

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:30:00

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 28 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input type="radio"/> |
| | Amendment 3 <input checked="" type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:23:08

Generated On: 09 Jun 2021 17:16:42

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 00:55:16

Generated On: 09 Jun 2021 17:16:42

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Condition | GENERALIZED OSTEOARTHRITIS |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Condition | OBESITY - MORBID |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Condition | VESICOURETERAL REFLUX DISEASE |
| Start date (dd MMM yyyy) | (b) (6) 1965 |
| 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 1968 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | (b) (6) 1965 |
| Start Year (derived) | 1965 |
| Stop Month and Year (derived) | JAN 1968 |
| Stop Year (derived) | 1968 |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Condition | VESICOURETERAL REFLUX DISEASE CORRECTION SURGERY |
| Start date (dd MMM yyyy) | UN UNK 1968 |
| 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 1968 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1968 |
| Start Year (derived) | 1968 |
| Stop Month and Year (derived) | JAN 1968 |
| Stop Year (derived) | 1968 |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Condition | GANGLION CYST LEFT WRIST |
| 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 (9)

Data signed: (b) (4) 17 Feb 2021 00:39:05

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Condition | EXCISION OF GANGLION CYST OF LEFT WRIST |
| 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 |

US3372284

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:33:16

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 28 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:12 (24 HR) |
| Vital Signs Date and Time (derived) | 28 AUG 2020 10:12 |
| Height (<i>xxx.x</i>) | 165.1 cm |
| Weight (<i>xxx.x</i>) | 146.4 kg |
| BMI (<i>xxx.x</i>) | 53.70898 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) 17 Feb 2021 01:11:01

Generated On: 09 Jun 2021 17:16:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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) 16 Feb 2021 18:02:44

Generated On: 09 Jun 2021 17:16:42

Date of assessment (dd MMM yyyy) 28 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) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:21:18

Generated On: 09 Jun 2021 17:16:42

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) 17 Feb 2021 02:21:18

Generated On: 09 Jun 2021 17:16:42

| | |
|--|-------|
| 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) 17 Feb 2021 03:17:01

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 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) 17 Feb 2021 02:04:32

Generated On: 09 Jun 2021 17:16:42

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 145023

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:49:36

Generated On: 09 Jun 2021 17:16:42

| | |
|--------|---------------|
| 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) 17 Feb 2021 03:49:36

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| 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) | 28 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:12 (24 HR) |
| Vital Signs Date and Time (derived) | 28 AUG 2020 10:12 |
| Temperature (xxx.x) | 36 C |
| 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) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:49:36

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 28 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:07 (24 HR) |
| Vital Signs Date and Time (derived) | 28 AUG 2020 12:07 |
| Temperature (xxx.x) | 36.1 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 77 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 133 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:11:01

Generated On: 09 Jun 2021 17:16:42

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) 16 Feb 2021 23:47:10

Generated On: 09 Jun 2021 17:16:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 11:35

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) 17 Feb 2021 00:06:54

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 AUG 2020 |
| Collection time (00:00-23:59) | 10:46 (24 HR) |
| Collection date and time (derived) | 28 AUG 2020 10:46 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:23:07

Generated On: 09 Jun 2021 17:16:42

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 28 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:38 | 28 AUG 2020 10:38 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

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: 09 Jun 2021 17:16:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:06

PC Open Date & Time

28 AUG 2020 11:55

PC Close Date & Time

28 AUG 2020 14:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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 | 28 AUG 2020 17:46 |
| PC Open Date & Time | 28 AUG 2020 15:20 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

98.2 °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

29 AUG 2020 12:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:44

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

97.1 °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 12:05

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:09

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

28 AUG 2020 12:07

PC Open Date & Time

28 AUG 2020 11:55

PC Close Date & Time

28 AUG 2020 14:25

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 17:46

PC Open Date & Time

28 AUG 2020 15:20

PC Close Date & Time

29 AUG 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

29 AUG 2020 12:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

30 AUG 2020 12:44

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

31 AUG 2020 12:01

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

01 SEP 2020 12:05

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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

02 SEP 2020 12:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

03 SEP 2020 12:09

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 AUG 2020 12:08 |
| PC Open Date & Time | 28 AUG 2020 11:55 |
| PC Close Date & Time | 28 AUG 2020 14:25 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 AUG 2020 17:47 |
| PC Open Date & Time | 28 AUG 2020 15:20 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 ☒

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 AUG 2020 12:08 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 ☒

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EAB) (1725)

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 12:45 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 31 AUG 2020 12:02 |
| PC Open Date & Time | 31 AUG 2020 12:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 3006

EAB) (1725)

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 ☒

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 12:04 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

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EAB) (1725)

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 SEP 2020 12:10 |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3372284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:24:16

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:24:16

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:16 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 11:16 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:24:16

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| 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) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 13:35 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 13:35 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 149 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:24:16

Generated On: 09 Jun 2021 17:16:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:24:16

Generated On: 09 Jun 2021 17:16:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 12:55 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 12:55

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

US3372284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:24:16

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 SEP 2020 |
| Collection time (00:00-23:59) | 12:27 (24 HR) |
| Collection date and time (derived) | 28 SEP 2020 12:27 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:23:07

Generated On: 09 Jun 2021 17:16:42

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 28 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:29 | 28 SEP 2020 11:29 |
| Nasopharyngeal Swab 2 | No | | |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 13:40

PC Open Date & Time

28 SEP 2020 13:15

PC Close Date & Time

28 SEP 2020 15:45

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐
No ☒

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 28 SEP 2020 18:10 |
| PC Open Date & Time | 28 SEP 2020 16:40 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 13:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

97.7 °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

30 SEP 2020 12:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:03

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

02 OCT 2020 12:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 OCT 2020 12:26

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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 OCT 2020 12:49

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 13:41

PC Open Date & Time

28 SEP 2020 13:15

PC Close Date & Time

28 SEP 2020 15:45

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 18:11

PC Open Date & Time

28 SEP 2020 16:40

PC Close Date & Time

29 SEP 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

29 SEP 2020 13:03

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

30 SEP 2020 12:05

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

01 OCT 2020 12:03

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

02 OCT 2020 12:04

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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

03 OCT 2020 12:27

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

04 OCT 2020 12:50

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 13:42 |
| PC Open Date & Time | 28 SEP 2020 13:15 |
| PC Close Date & Time | 28 SEP 2020 15:45 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 18:11 |
| PC Open Date & Time | 28 SEP 2020 16:40 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 ☒

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 SEP 2020 13:03 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 3006

EAB) (1725)

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 12:05 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

101 of 3006

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 OCT 2020 12:04 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 OCT 2020 12:04 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 OCT 2020 12:28 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 ☒

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 OCT 2020 12:50 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3372284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:05:02

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 23 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:05:02

Generated On: 09 Jun 2021 17:16:42

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) _____

US3372284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:05:02

Generated On: 09 Jun 2021 17:16:42

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.

US3372284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:05:02

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 23 OCT 2020 |
| Collection time (00:00-23:59) | 11:08 (24 HR) |
| Collection date and time (derived) | 23 OCT 2020 11:08 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| 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 | 28 OCT 2020 12:04:26 |
| Patient Cloud Open Date & Time | 28 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 01 NOV 2020 23:59 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

04 NOV 2020 12:03:48

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

11 NOV 2020 12:00:54

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 10:37:53

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 29 NOV 2020 13:01:28 |
| Patient Cloud Open Date & Time | 29 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 03 DEC 2020 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 103 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 DEC 2020 17:44:41 |
| Patient Cloud Open Date & Time | 06 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 10 DEC 2020 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 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 | 13 DEC 2020 12:57:13 |
| Patient Cloud Open Date & Time | 13 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 17 DEC 2020 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

20 DEC 2020 11:03:55

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 DEC 2020 11:00:33 |
| Patient Cloud Open Date & Time | 27 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 31 DEC 2020 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

03 JAN 2021 08:09:19

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

10 JAN 2021 11:06:55

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

17 JAN 2021 11:00:36

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

24 JAN 2021 11:01:42

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 06:26:50

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

07 FEB 2021 11:05:43

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

14 FEB 2021 11:00:30

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 11:46:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

28 FEB 2021 10:52:55

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 11:05:47

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

14 MAR 2021 10:40:26

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

21 MAR 2021 11:00:49

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

28 MAR 2021 08:05:32

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 08:50:04

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

11 APR 2021 05:58:40

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 07:39:09

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

25 APR 2021 06:46:44

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

02 MAY 2021 11:00:52

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 <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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 24 JUN 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 <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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 19 AUG 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 09 SEP 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 390 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 07 OCT 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 21 OCT 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 <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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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="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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 09 DEC 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2021 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 30 DEC 2021 23:59 |
|---|-------------------|

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 09 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 13 JAN 2022 23:59 |

(b)

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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="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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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27 JAN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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03 FEB 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

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US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 <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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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17 FEB 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 <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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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24 FEB 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

Date and time of submission

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03 MAR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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°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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

| | |
|---|-------------------|
| Date and time of submission | |
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US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

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24 MAR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

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Folder: New Safety Follow Up Diary (1)

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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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27 MAR 2022 00:01

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31 MAR 2022 23:59

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Form: Safety Follow Up Diary

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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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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="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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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="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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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 <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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 14 JUL 2022 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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°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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 719 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 733 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| TIMEPOINT | DAY 747 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 20 OCT 2022 23:59 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

| 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"/> |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3372284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:16:42

| 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 | | 28 FEB 2021 10:52:43 |

US3372284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:32

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:38:48

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:03:03

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 22:50:43

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 22:50:43

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 26 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 |
|------------|--------|

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 21:37:31

Generated On: 09 Jun 2021 17:16:42

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) _____

US3372284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

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.

US3372284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 26 MAR 2021 |
| Collection time (00:00-23:59) | 11:58 (24 HR) |
| Collection date and time (derived) | 26 MAR 2021 11:58 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 27 Apr 2021 01:41:13

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 27 Apr 2021 01:41:13

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Feb 2021 23:03:57

Generated On: 09 Jun 2021 17:16:42

| | |
|--|--|
| Date of Contact | 03 DEC 2020 |
| Time of Contact | 08:29 |
| Date and Time of Contact (derived) | 03 DEC 2020 08:29 |
| Type of Contact | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div> |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 30 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 01 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 02 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 03 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.5 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
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| EAB) (1725) | | |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 04 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 99.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 05 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 99.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 06 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 99.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 07 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 99.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 08 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 98.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 09 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (10)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 10 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 96.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 11 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 95 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 12 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 13 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.9 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 14 DEC 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|------|
| O2 Saturation | 98 % |
|---------------|------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|--------|
| Temperature | 97.5 F |
|-------------|--------|

| | |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|-------|---------------------------------------|
| Cough | None <input type="radio"/> |
| | Mild <input checked="" type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 99.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 16 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 98.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 17 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 18 DEC 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
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| EAB) (1725) | | |

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Form: Symptom Log (19)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 17 Feb 2021 02:55:17

Generated On: 09 Jun 2021 17:16:42

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Feb 2021 23:01:24

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Date of Visit | 03 DEC 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 03 DEC 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 1 |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Feb 2021 23:03:57

Generated On: 09 Jun 2021 17:16:42

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Feb 2021 23:03:57

Generated On: 09 Jun 2021 17:16:42

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

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Feb 2021 23:03:57

Generated On: 09 Jun 2021 17:16:42

Hepatic Dysfunction? Yes ☐
No ☐

Start Date

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☐

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Feb 2021 23:03:56

Generated On: 09 Jun 2021 17:16:42

| | |
|--|--|
| Date of Contact | 16 NOV 2020 |
| Time of Contact | 09:10 |
| Date and Time of Contact (derived) | 16 NOV 2020 09:10 |
| Type of Contact | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div> |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 14 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|-----------------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 | | 408 of 3006 |
| EAB) (1725) | | |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 16 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 17 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.7 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 18 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.7 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 94 % | |
| O2 Saturation Units | % | |
| Temperature | 98.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 12:40:01

Generated On: 09 Jun 2021 17:16:42

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Feb 2021 23:01:24

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Date of Visit | 17 NOV 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 17 NOV 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 0 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Feb 2021 23:59:37

Generated On: 09 Jun 2021 17:16:42

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Feb 2021 02:51:31

Generated On: 09 Jun 2021 17:16:42

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 19 NOV 2020 |
| Day 5 | No | |
| Day 7 | No | |
| Day 9 | No | |
| Day 14 | No | |
| Day 21 | No | |
| Day 28 | No | |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 17 Feb 2021 02:51:31

Generated On: 09 Jun 2021 17:16:42

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 05 DEC 2020 |
| Day 5 | Yes | 07 DEC 2020 |
| Day 7 | Yes | 09 DEC 2020 |
| Day 9 | Yes | 11 DEC 2020 |
| Day 14 | Yes | 16 DEC 2020 |
| Day 21 | Yes | 23 DEC 2020 |
| Day 28 | Yes | 30 DEC 2020 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:17:01

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:33:16

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 NOV 2020 |
| Time of assessment (00:00-23:59) | 11:10 (24 HR) |
| Vital Signs Date and Time (derived) | 17 NOV 2020 11:10 |
| Height (xxx.x) | 65 in |
| Weight (xxx.x) | ND - Not Done |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 97 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 150 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 95 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:11:01

Generated On: 09 Jun 2021 17:16:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 NOV 2020

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

US3372284

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Feb 2021 17:14:01

Generated On: 09 Jun 2021 17:16:42

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 NOV 2020

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:17:01

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 03 DEC 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input checked="" type="radio"/> |
| | Clinic <input type="radio"/> |
| Folder OID | SICKD1 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:33:16

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 03 DEC 2020 |
| Time of assessment (00:00-23:59) | 11:35 (24 HR) |
| Vital Signs Date and Time (derived) | 03 DEC 2020 11:35 |
| Height (xxx.x) | ND - Not Done |
| Weight (xxx.x) | 313.6 lb |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 94 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 19 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 150 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:11:01

Generated On: 09 Jun 2021 17:16:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 DEC 2020

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

US3372284

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Feb 2021 17:14:01

Generated On: 09 Jun 2021 17:16:42

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

03 DEC 2020

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:17:01

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 30 DEC 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD28 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 21:04:38

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 30 DEC 2020 |
| Time of assessment (00:00-23:59) | 09:11 (24 HR) |
| Vital Signs Date and Time (derived) | 30 DEC 2020 09:11 |
| Temperature (xxx.x) | 36 C |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 89 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 148 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:11:01

Generated On: 09 Jun 2021 17:16:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3372284

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Feb 2021 17:14:01

Generated On: 09 Jun 2021 17:16:42

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 DEC 2020

US3372284

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:17:01

Generated On: 09 Jun 2021 17:16:42

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

US3372284

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

Form: Unblinding

Data signed: (b) (4) 16 Mar 2021 19:26:26

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 28 JAN 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 28 JAN 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3372284

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:49:36

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |

US3372284

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:49:36

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 28 JAN 2021 |
| Time of assessment (00:00-23:59) | 09:05 (24 HR) |
| Vital Signs Date and Time (derived) | 28 JAN 2021 09:05 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:49:36

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| 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) | 28 JAN 2021 |
| Time of assessment (00:00-23:59) | 10:30 (24 HR) |
| Vital Signs Date and Time (derived) | 28 JAN 2021 10:30 |
| Temperature (xxx.x) | 36.4 C |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 135 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 90 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:11:01

Generated On: 09 Jun 2021 17:16:42

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.

US3372284

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:47:10

Generated On: 09 Jun 2021 17:16:42

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

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

Treatment Date and Time (derived) 28 JAN 2021 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

US3372284

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:06:54

Generated On: 09 Jun 2021 17:16:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

08:49 (24 HR)

Collection date and time (derived)

28 JAN 2021 08:49

US3372284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:42:04

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------------|--------------------------------------|
| 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) | 08:40 |
| Collection Date and Time (derived) | 28 JAN 2021 08:40 |

US3372284

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:01:32

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:26:26

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:26:26

Generated On: 09 Jun 2021 17:16:42

| | |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Continuing Flag | 1 |
| OLD29 Placebo Flag | 1 |

US3372284

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 19:26:25

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 25 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Mar 2021 19:26:25

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 FEB 2021 |
| Time of assessment (00:00-23:59) | 08:46 (24 HR) |
| Vital Signs Date and Time (derived) | 25 FEB 2021 08:46 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 92 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Mar 2021 19:26:25

Generated On: 09 Jun 2021 17:16:42

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 FEB 2021 |
| Time of assessment (00:00-23:59) | 10:18 (24 HR) |
| Vital Signs Date and Time (derived) | 25 FEB 2021 10:18 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (xxx) | 79 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) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3372284

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 19:26:25

Generated On: 09 Jun 2021 17:16:42

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.

US3372284

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Mar 2021 19:26:25

Generated On: 09 Jun 2021 17:16:42

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 09:45 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 09:45

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

US3372284

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:26:25

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 19:26:26

Generated On: 09 Jun 2021 17:16:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372284

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:26:26

Generated On: 09 Jun 2021 17:16:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372284

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 26 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 | OLD57 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 26 MAR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 11:45 (24 HR) |
| Vital Signs Date and Time (derived) | 26 MAR 2021 11:45 |
| Temperature (<i>xxx.x</i>) | 36.5 C |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | FOREHEAD |
| Pulse (<i>xxx</i>) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 123 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3372284

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

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.

US3372284

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 13:33:37

Generated On: 09 Jun 2021 17:16:42

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 26 MAR 2021 |
| Collection time (00:00-23:59) | 11:58 (24 HR) |
| Collection date and time (derived) | 26 MAR 2021 11:58 |

US3372284

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:48:36

Generated On: 09 Jun 2021 17:16:42

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | |
|--|--|
| AEID | |
| Adverse event | MILD COUGH |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 14 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 18 DEC 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | |
|--|--|
| AEID | USA-US056-2020-MRNA-1273-P30 1000009 |
| Adverse event | COVID-19 |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Start date (dd MMM yyyy) | 30 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 18 DEC 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input 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 | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | True |
| 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SUBJECT TESTED POSITIVE FOR COVID-19 |
| 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) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:48:45

Generated On: 09 Jun 2021 17:16:42

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

Yes ☒

No ☐

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

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED
OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | | |
|--|--------------------------|----------------------------------|
| | 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 2008 |
| 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"/> |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 8 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 8 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 27 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 27 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PYREXIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 06 DEC 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 10 DEC 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

Name of Medication TUSSIN-CF

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:39:22

Generated On: 09 Jun 2021 17:16:42

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 10 DEC 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 17 DEC 2020 |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3372284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:19:05

Generated On: 09 Jun 2021 17:16:42

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3372284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:16:42

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

US3372284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:16:42

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 ☐

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 30 Mar 2021 14:28:52

Generated On: 09 Jun 2021 17:16:42

| | |
|--|--|
| SAEID | USA-US056-2020-MRNA-1273-P301000009 |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | MIRA |
| Investigator's Last Name | BARON |
| Site Address: Street | 2277 PALM BEACH LAKES BLVD |
| Site Address: City | WEST PALM BEACH |
| Site Address: State | |
| Site Address: Postal Code | 33409 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Mar 2021 14:28:52

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| SAEID | USA-US056-2020-MRNA-1273-P301000009 |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | MIRA |
| Investigator's Last Name | BARON |
| Site Address: Street | 2277 PALM BEACH LAKES BLVD |
| Site Address: City | WEST PALM BEACH |
| Site Address: State | |
| Site Address: Postal Code | 33409 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 14/DEC/2020 13:10 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Mar 2021 14:28:52

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| SAEID | USA-US056-2020-MRNA-1273-P301000009 |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | MIRA |
| Investigator's Last Name | BARON |
| Site Address: Street | 2277 PALM BEACH LAKES BLVD |
| Site Address: City | WEST PALM BEACH |
| Site Address: State | |
| Site Address: Postal Code | 33409 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 23/DEC/2020 13:00 |
| 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 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Mar 2021 14:28:52

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| SAEID | USA-US056-2020-MRNA-1273-P301000009 |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | MIRA |
| Investigator's Last Name | BARON |
| Site Address: Street | 2277 PALM BEACH LAKES BLVD |
| Site Address: City | WEST PALM BEACH |
| Site Address: State | |
| Site Address: Postal Code | 33409 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 16/FEB/2021 20:35 |
| 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 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Mar 2021 14:28:52

Generated On: 09 Jun 2021 17:16:42

| | |
|---|--|
| SAEID | USA-US056-2020-MRNA-1273-P301000009 |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | MIRA |
| Investigator's Last Name | BARON |
| Site Address: Street | 2277 PALM BEACH LAKES BLVD |
| Site Address: City | WEST PALM BEACH |
| Site Address: State | |
| Site Address: Postal Code | 33409 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 30/MAR/2021 09:43 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3372284 (Prod: Palm Beach Research Center)

US3372284

Form: Participant Creation

Generated On: 09 Jun 2021 17:16:42

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:47:17 |
| User entered 'US3372284' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 13:24:26 |

US3372284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:07 |

US3372284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered '28 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 13:24:27 |

US3372284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:07 |

US3372284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'SCRN' | System | 28 Aug 2020 15:05:07 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered (b) (6) 1965' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 13:24:28 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '55' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'YEARS' | System | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '55' | System | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered 'Female (F)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:16:42

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:10:43 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:36 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered '28 Aug 2020' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Aug 2020' | System | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2020' | System | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered 'Amendment 3 (3)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:05:54 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:30:00 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 13:24:27 |

US3372284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:16:42

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'I' | System | 28 Aug 2020 15:06:00 |

US3372284

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:23:08 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:00 |

US3372284

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:16:42

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:55:16 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:43:15 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| Data point term sent to Coder | System | 11 Oct 2020 22:44:03 |
| User entered 'generalized osteoarthritis' | Peter Jacob (b) (4) | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2008' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2008' | System | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2008' | System | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered empty. | System | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered empty. | System | 11 Oct 2020 22:43:41 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| Data point term sent to Coder | System | 11 Oct 2020 22:45:04 |
| User entered 'obesity - morbid' | Peter Jacob (b) (4) | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2008' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2008' | System | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2008' | System | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered empty. | System | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered empty. | System | 11 Oct 2020 22:44:27 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| Data point term sent to Coder | System | 11 Oct 2020 22:45:04 |
| User entered 'postmenopause' | Peter Jacob (b) (4) | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2010' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2010' | System | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2010' | System | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered empty. | System | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered empty. | System | 11 Oct 2020 22:44:41 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:45:20 |
| Data point term sent to Coder | System | 11 Oct 2020 22:45:04 |
| User entered 'uterine fibroids' | Peter Jacob (b) (4) | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2005' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| 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). | (b) (4) System | 11 Oct 2020 22:45:12 |
| User entered 'No (N)' reason for change: Data Entry Error | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:45:12 |
| 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 | 11 Oct 2020 22:44:55 |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2005' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2005' | System | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2005' | System | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2005' | System | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2005' | System | 11 Oct 2020 22:44:55 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Myomectomy, LLT: Uterine myomectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:46:21 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:46:21 |
| Data point term sent to Coder | System | 11 Oct 2020 22:46:05 |
| User entered 'uterine myomectomy' | Peter Jacob (b) (4) | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2005' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 2005' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2005' | System | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2005' | System | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 2005' | System | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '2005' | System | 11 Oct 2020 22:45:36 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Bladder reflux conditions, PT: Vesicoureteric reflux, LLT: Vesicoureteral reflux - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Oct 2020 05:10:34 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Oct 2020 05:10:34 |
| Data point term sent to Coder | System | 11 Oct 2020 22:48:05 |
| User entered 'Vesicoureteral reflux disease' | Peter Jacob (b) (4) | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered (b) (6) 1965' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1968' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered (b) (6) 1965' | System | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1965' | System | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1968' | System | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1968' | System | 11 Oct 2020 22:47:20 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Ureteric therapeutic procedures, PT: Vesicoureteral reflux surgery, LLT: Vesicoureteral reflux surgery - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Oct 2020 05:11:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Oct 2020 05:11:36 |
| Data point term sent to Coder | System | 11 Oct 2020 22:48:07 |
| User entered 'Vesicoureteral reflux disease correction surgery' | Peter Jacob (b) (4) | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1968' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1968' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1968' | System | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1968' | System | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1968' | System | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1968' | System | 11 Oct 2020 22:48:02 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Synovial cyst, LLT: Ganglion cyst - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:49:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Oct 2020 22:49:22 |
| Data point term sent to Coder | System | 11 Oct 2020 22:49:07 |
| User entered 'ganglion cyst left wrist' | Peter Jacob (b) (4) | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1982' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1982' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1982' | System | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1982' | System | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1982' | System | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1982' | System | 11 Oct 2020 22:48:24 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Synovial cyst removal, LLT: Ganglion removal - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Oct 2020 05:03:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Oct 2020 05:03:26 |
| Data point term sent to Coder | System | 11 Oct 2020 22:50:08 |
| User entered 'excision of ganglion cyst of left wrist' | Peter Jacob (b) (4) | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1982' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered 'un UNK 1982' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:39:06 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1982' | System | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1982' | System | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'Jan 1982' | System | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '1982' | System | 11 Oct 2020 22:49:10 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered '10:12' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '28 Aug 2020 10:12' | System | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered '165.1' cm | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| DataPoint set to visible. | (b) (4) System | 28 Aug 2020 15:06:00 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered '146.4' kg | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| DataPoint set to visible. | (b) (4) System | 28 Aug 2020 15:06:00 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered '53.70898' | System | 08 Sep 2020 21:25:56 |
| DataPoint set to visible. | System | 28 Aug 2020 15:06:00 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'kg/m2' | System | 08 Sep 2020 21:25:56 |
| DataPoint set to visible. | System | 28 Aug 2020 15:06:00 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Sep 2020 13:10:14 |
| Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:30:26 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:30:22 |
| User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 11:56:53 |
| User entered '36' C | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Peter Jacob (b) (4) | 28 Sep 2020 14:30:22 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| | (b) (4) | |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:30:22 |
| User entered '78' | Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| | (b) (4) | |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'bpm' | System | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:30:22 |
| User entered '17' | Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| | (b) (4) | |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'breaths/min' | System | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:30:22 |
| User entered '134' | Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| | (b) (4) | |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'mmHg' | System | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:30:22 |
| User entered '86' | Peter Jacob (b) (4) | 08 Sep 2020 21:25:56 |
| | (b) (4) | |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User entered 'mmHg' | System | 08 Sep 2020 21:25:56 |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| | | |

US3372284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |

US3372284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:26:33 |

US3372284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:33 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

If No, what is the reason?

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| 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) | 13 Oct 2020 18:14:26 |
| 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 'data updated' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 23:14:40 |
| 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) | 09 Oct 2020 12:33:39 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

[If Partner medically sterile or Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered 'un UNK 2010' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:16:42

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:02:44 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:26:50 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered '0' | Peter Jacob (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered '0' | Peter Jacob (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered 'I' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:16:42

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 01:02:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:21:18 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:27:10 |

US3372284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:27 |

US3372284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered '28 Aug 2020' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:27 |

US3372284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:27 |

US3372284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'VISIT1' | System | 28 Aug 2020 15:06:27 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered '28 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 15:05:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered '145023' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 15:05:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered '>=18 and <65 years and at risk (2)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 28 Aug 2020 15:05:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:06:49 |

US3372284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:16:42

Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:04:32 |
| User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Oct 2020 16:57:56 |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 29 Oct 2020 16:51:30 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 29 Oct 2020 16:51:23 |
| User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 16:40:21 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 08:23:46 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 08:23:45 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

Height

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Sep 2020 13:26:01 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:24:04 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:24:00 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 11:56:45 |
| User entered '165.1' cm | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:24:00 |
| User entered '146.4' kg | Peter Jacob (b) (4) | 08 Sep 2020 21:28:09 |
| | (b) (4) | |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Height](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Sep 2020 13:26:01 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:24:04 |
| answered with 'data updated' (Site from DM). | | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:24:00 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 11:56:45 |
| User entered '165.1' cm | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:24:00 |
| User entered '146.4' kg | Peter Jacob (b) (4) | 08 Sep 2020 21:28:09 |
| | (b) (4) | |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '10:12' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Aug 2020 10:12' | System | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '36' C | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Oral (Oral)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '78' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'bpm' | System | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '17' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'breaths/min' | System | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '134' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '86' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

Height

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 29 Sep 2020 13:26:01 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:24:04 |
| answered with 'data updated' (Site from DM). | | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Peter Jacob (b) (4) (b) (4) | 28 Sep 2020 14:24:00 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 11:56:45 |
| User entered '165.1' cm | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:09 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 28 Sep 2020 14:24:00 |
| User entered '146.4' kg | Peter Jacob (b) (4) | 08 Sep 2020 21:28:09 |
| | (b) (4) | |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '12:07' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Aug 2020 12:07' | System | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '36.1' C | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Oral (Oral)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '77' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'bpm' | System | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '17' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'breaths/min' | System | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '133' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '81' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 08 Sep 2020 21:28:34 |

US3372284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:39 |

US3372284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered '28 Aug 2020' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered '11:35' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Aug 2020 11:35' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4) (b) (4), (b) (6) | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'ONCE' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'INTRAMUSCULAR' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:06:54 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:50 |

US3372284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:06:54 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:50 |

US3372284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:06:54 |
| User entered '10:46' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:50 |

US3372284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Aug 2020 10:46' | System | 08 Sep 2020 21:28:50 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered '28 Aug 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered '10:38' | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Aug 2020 10:38' | System | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 08 Sep 2020 21:28:58 |

US3372284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Alexandra Arango (b) (4) | 08 Sep 2020 17:06:03 |

US3372284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'I' | System | 08 Sep 2020 17:06:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:05:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '93515856-9f42-4f4e-95f9-217deddae01b' | System | 28 Aug 2020 16:06:37 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 16:06:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:05:42', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '93515856-9f42-4f4e-95f9-217deddae01b' User entered '97.5' | System | 28 Aug 2020 16:06:37 |
| | System | 28 Aug 2020 16:06:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:06:02', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '93515856-9f42-4f4e-95f9-217deddae01b' | System | 28 Aug 2020 16:06:37 |
| User entered 'No (N)' | System | 28 Aug 2020 16:06:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:06:10', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '93515856-9f42-4f4e-95f9-217deddae01b' | System | 28 Aug 2020 16:06:37 |
| User entered '28 Aug 2020 12:06' | System | 28 Aug 2020 16:06:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 11:55' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 14:25' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:45:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a6c1a3e0-478e-4f2f-921f-5910abd1806a' | System | 28 Aug 2020 21:46:17 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 21:46:17 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:45:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a6c1a3e0-478e-4f2f-921f-5910abd1806a' | System | 28 Aug 2020 21:46:17 |
| User entered '98.2' | System | 28 Aug 2020 21:46:17 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:06', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a6c1a3e0-478e-4f2f-921f-5910abd1806a' | System | 28 Aug 2020 21:46:17 |
| User entered 'No (N)' | System | 28 Aug 2020 21:46:17 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a6c1a3e0-478e-4f2f-921f-5910abd1806a' | System | 28 Aug 2020 21:46:17 |
| User entered '28 Aug 2020 17:46' | System | 28 Aug 2020 21:46:17 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 15:20' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 2' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:01:31', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '867c50d0-ff71-406e-853a-10aea48fe2b7' | System | 29 Aug 2020 16:03:37 |
| User entered 'Yes (Y)' | System | 29 Aug 2020 16:03:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:02:42', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '867c50d0-ff71-406e-853a-10aea48fe2b7' | System | 29 Aug 2020 16:03:37 |
| User entered '98.2' | System | 29 Aug 2020 16:03:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:02:59', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '867c50d0-ff71-406e-853a-10aea48fe2b7' | System | 29 Aug 2020 16:03:37 |
| User entered 'No (N)' | System | 29 Aug 2020 16:03:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:03:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '867c50d0-ff71-406e-853a-10aea48fe2b7' | System | 29 Aug 2020 16:03:37 |
| User entered '29 Aug 2020 12:03' | System | 29 Aug 2020 16:03:37 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 3' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:43:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '18bc2140-386a-4a2f-a925-c7c3b1e2a498' | System | 30 Aug 2020 16:44:23 |
| User entered 'Yes (Y)' | System | 30 Aug 2020 16:44:23 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:43:46', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '18bc2140-386a-4a2f-a925-c7c3b1e2a498' | System | 30 Aug 2020 16:44:23 |
| User entered '97.8' | System | 30 Aug 2020 16:44:23 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:43:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '18bc2140-386a-4a2f-a925-c7c3b1e2a498' | System | 30 Aug 2020 16:44:23 |
| User entered 'No (N)' | System | 30 Aug 2020 16:44:23 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:01', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '18bc2140-386a-4a2f-a925-c7c3b1e2a498' | System | 30 Aug 2020 16:44:23 |
| User entered '30 Aug 2020 12:44' | System | 30 Aug 2020 16:44:23 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '31 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 4' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f56ba45-ccd4-4505-b6e3-b4c4423441e3' | System | 31 Aug 2020 16:02:51 |
| User entered 'Yes (Y)' | System | 31 Aug 2020 16:02:51 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:14', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f56ba45-ccd4-4505-b6e3-b4c4423441e3' | System | 31 Aug 2020 16:02:51 |
| User entered '98.6' | System | 31 Aug 2020 16:02:51 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:17', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f56ba45-ccd4-4505-b6e3-b4c4423441e3' | System | 31 Aug 2020 16:02:51 |
| User entered 'No (N)' | System | 31 Aug 2020 16:02:51 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f56ba45-ccd4-4505-b6e3-b4c4423441e3' | System | 31 Aug 2020 16:02:51 |
| User entered '31 Aug 2020 12:01' | System | 31 Aug 2020 16:02:51 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '31 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 5' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:03', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd3656c0a-5272-43a3-b4b5-cca725aa3478' | System | 01 Sep 2020 16:05:27 |
| User entered 'Yes (Y)' | System | 01 Sep 2020 16:05:27 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:08', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd3656c0a-5272-43a3-b4b5-cca725aa3478' | System | 01 Sep 2020 16:05:27 |
| User entered '97.1' | System | 01 Sep 2020 16:05:27 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:11', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd3656c0a-5272-43a3-b4b5-cca725aa3478' | System | 01 Sep 2020 16:05:27 |
| User entered 'No (N)' | System | 01 Sep 2020 16:05:27 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:15', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd3656c0a-5272-43a3-b4b5-cca725aa3478' | System | 01 Sep 2020 16:05:27 |
| User entered '01 Sep 2020 12:05' | System | 01 Sep 2020 16:05:27 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 6' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:03:12', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bd541fd4-eadf-4ebf-aa0c-c94eb438f7cf' | System | 02 Sep 2020 16:04:38 |
| User entered 'Yes (Y)' | System | 02 Sep 2020 16:04:38 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:03:19', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bd541fd4-eadf-4ebf-aa0c-c94eb438f7cf' | System | 02 Sep 2020 16:04:38 |
| User entered '97.6' | System | 02 Sep 2020 16:04:38 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:03:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bd541fd4-eadf-4ebf-aa0c-c94eb438f7cf' | System | 02 Sep 2020 16:04:38 |
| User entered 'No (N)' | System | 02 Sep 2020 16:04:38 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:03:58', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bd541fd4-eadf-4ebf-aa0c-c94eb438f7cf' | System | 02 Sep 2020 16:04:38 |
| User entered '02 Sep 2020 12:03' | System | 02 Sep 2020 16:04:38 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 7' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:08:17', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dcbd5bce-defa-4d26-9a32-fd81eb365b45' | System | 03 Sep 2020 16:09:20 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 16:09:20 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:08:22', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dcbd5bce-defa-4d26-9a32-fd81eb365b45' | System | 03 Sep 2020 16:09:20 |
| User entered '98.3' | System | 03 Sep 2020 16:09:20 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dcbd5bce-defa-4d26-9a32-fd81eb365b45' | System | 03 Sep 2020 16:09:20 |
| User entered 'No (N)' | System | 03 Sep 2020 16:09:20 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dcbd5bce-defa-4d26-9a32-fd81eb365b45' | System | 03 Sep 2020 16:09:20 |
| User entered '03 Sep 2020 12:09' | System | 03 Sep 2020 16:09:20 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:06:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '60e294f4-3b4c-4566-997c-8a7c0ac93398' | System | 28 Aug 2020 16:07:25 |
| User entered 'None (1)' | System | 28 Aug 2020 16:07:25 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:06:27', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '60e294f4-3b4c-4566-997c-8a7c0ac93398' | System | 28 Aug 2020 16:07:25 |
| User entered 'No (N)' | System | 28 Aug 2020 16:07:25 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:06:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '60e294f4-3b4c-4566-997c-8a7c0ac93398' | System | 28 Aug 2020 16:07:25 |
| User entered 'No (N)' | System | 28 Aug 2020 16:07:25 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '60e294f4-3b4c-4566-997c-8a7c0ac93398' | System | 28 Aug 2020 16:07:25 |
| User entered 'None (1)' | System | 28 Aug 2020 16:07:25 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:12', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '60e294f4-3b4c-4566-997c-8a7c0ac93398' | System | 28 Aug 2020 16:07:25 |
| User entered '28 Aug 2020 12:07' | System | 28 Aug 2020 16:07:25 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 11:55' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 14:25' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '4692c0a5-915f-4db8-9ad6-ce1e38775b37' | System | 28 Aug 2020 21:47:03 |
| User entered 'None (1)' | System | 28 Aug 2020 21:47:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:30', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '4692c0a5-915f-4db8-9ad6-ce1e38775b37' | System | 28 Aug 2020 21:47:03 |
| User entered 'No (N)' | System | 28 Aug 2020 21:47:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '4692c0a5-915f-4db8-9ad6-ce1e38775b37' | System | 28 Aug 2020 21:47:03 |
| User entered 'No (N)' | System | 28 Aug 2020 21:47:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:52', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '4692c0a5-915f-4db8-9ad6-ce1e38775b37' | System | 28 Aug 2020 21:47:03 |
| User entered 'None (1)' | System | 28 Aug 2020 21:47:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:46:57', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '4692c0a5-915f-4db8-9ad6-ce1e38775b37' | System | 28 Aug 2020 21:47:03 |
| User entered '28 Aug 2020 17:46' | System | 28 Aug 2020 21:47:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 15:20' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 2' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:06:52', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5f045585-224e-442d-9a09-a3a9cdb2f4d5' | System | 29 Aug 2020 16:07:31 |
| User entered 'None (1)' | System | 29 Aug 2020 16:07:31 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:06:59', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5f045585-224e-442d-9a09-a3a9cdb2f4d5' | System | 29 Aug 2020 16:07:31 |
| User entered 'No (N)' | System | 29 Aug 2020 16:07:31 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:06', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5f045585-224e-442d-9a09-a3a9cdb2f4d5' | System | 29 Aug 2020 16:07:31 |
| User entered 'No (N)' | System | 29 Aug 2020 16:07:31 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5f045585-224e-442d-9a09-a3a9cdb2f4d5' | System | 29 Aug 2020 16:07:31 |
| User entered 'None (1)' | System | 29 Aug 2020 16:07:31 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:27', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5f045585-224e-442d-9a09-a3a9cdb2f4d5' | System | 29 Aug 2020 16:07:31 |
| User entered '29 Aug 2020 12:07' | System | 29 Aug 2020 16:07:31 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 3' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:10', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b3fe67d1-2c52-4ff5-a412-80dab430cf49' | System | 30 Aug 2020 16:45:03 |
| User entered 'None (1)' | System | 30 Aug 2020 16:45:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:18', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b3fe67d1-2c52-4ff5-a412-80dab430cf49' | System | 30 Aug 2020 16:45:03 |
| User entered 'No (N)' | System | 30 Aug 2020 16:45:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:21', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b3fe67d1-2c52-4ff5-a412-80dab430cf49' | System | 30 Aug 2020 16:45:03 |
| User entered 'No (N)' | System | 30 Aug 2020 16:45:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b3fe67d1-2c52-4ff5-a412-80dab430cf49' | System | 30 Aug 2020 16:45:03 |
| User entered 'None (1)' | System | 30 Aug 2020 16:45:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b3fe67d1-2c52-4ff5-a412-80dab430cf49' | System | 30 Aug 2020 16:45:03 |
| User entered '30 Aug 2020 12:44' | System | 30 Aug 2020 16:45:03 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '31 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 4' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:28', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a8bde59c-ce48-4b76-8d83-21fde5f5098c' | System | 31 Aug 2020 16:03:21 |
| User entered 'None (1)' | System | 31 Aug 2020 16:03:21 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:31', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a8bde59c-ce48-4b76-8d83-21fde5f5098c' | System | 31 Aug 2020 16:03:21 |
| User entered 'No (N)' | System | 31 Aug 2020 16:03:21 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a8bde59c-ce48-4b76-8d83-21fde5f5098c' | System | 31 Aug 2020 16:03:21 |
| User entered 'No (N)' | System | 31 Aug 2020 16:03:21 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:47', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a8bde59c-ce48-4b76-8d83-21fde5f5098c' | System | 31 Aug 2020 16:03:21 |
| User entered 'None (1)' | System | 31 Aug 2020 16:03:21 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a8bde59c-ce48-4b76-8d83-21fde5f5098c' | System | 31 Aug 2020 16:03:21 |
| User entered '31 Aug 2020 12:01' | System | 31 Aug 2020 16:03:21 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '31 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 5' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'eb3d2eb7-de5a-4308-81fc-9939eb4427b1' | System | 01 Sep 2020 16:05:52 |
| User entered 'None (1)' | System | 01 Sep 2020 16:05:52 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'eb3d2eb7-de5a-4308-81fc-9939eb4427b1' | System | 01 Sep 2020 16:05:52 |
| User entered 'No (N)' | System | 01 Sep 2020 16:05:52 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:25', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'eb3d2eb7-de5a-4308-81fc-9939eb4427b1' | System | 01 Sep 2020 16:05:52 |
| User entered 'No (N)' | System | 01 Sep 2020 16:05:52 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'eb3d2eb7-de5a-4308-81fc-9939eb4427b1' | System | 01 Sep 2020 16:05:52 |
| User entered 'None (1)' | System | 01 Sep 2020 16:05:52 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:40', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'eb3d2eb7-de5a-4308-81fc-9939eb4427b1' | System | 01 Sep 2020 16:05:52 |
| User entered '01 Sep 2020 12:05' | System | 01 Sep 2020 16:05:52 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 6' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:06', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '70c0d87a-6099-4c3d-80c9-434a72bf913d' | System | 02 Sep 2020 16:04:53 |
| User entered 'None (1)' | System | 02 Sep 2020 16:04:53 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:08', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '70c0d87a-6099-4c3d-80c9-434a72bf913d' | System | 02 Sep 2020 16:04:53 |
| User entered 'No (N)' | System | 02 Sep 2020 16:04:53 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:11', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '70c0d87a-6099-4c3d-80c9-434a72bf913d' | System | 02 Sep 2020 16:04:53 |
| User entered 'No (N)' | System | 02 Sep 2020 16:04:53 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:22', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '70c0d87a-6099-4c3d-80c9-434a72bf913d' | System | 02 Sep 2020 16:04:53 |
| User entered 'None (1)' | System | 02 Sep 2020 16:04:53 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:25', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '70c0d87a-6099-4c3d-80c9-434a72bf913d' | System | 02 Sep 2020 16:04:53 |
| User entered '02 Sep 2020 12:04' | System | 02 Sep 2020 16:04:53 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 7' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:16', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc7b7e0b-9bb0-462d-81aa-834f1eb79f7e' | System | 03 Sep 2020 16:09:47 |
| User entered 'None (1)' | System | 03 Sep 2020 16:09:47 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:19', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc7b7e0b-9bb0-462d-81aa-834f1eb79f7e' | System | 03 Sep 2020 16:09:47 |
| User entered 'No (N)' | System | 03 Sep 2020 16:09:47 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:21', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc7b7e0b-9bb0-462d-81aa-834f1eb79f7e' | System | 03 Sep 2020 16:09:47 |
| User entered 'No (N)' | System | 03 Sep 2020 16:09:47 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc7b7e0b-9bb0-462d-81aa-834f1eb79f7e' | System | 03 Sep 2020 16:09:47 |
| User entered 'None (1)' | System | 03 Sep 2020 16:09:47 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:35', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc7b7e0b-9bb0-462d-81aa-834f1eb79f7e' | System | 03 Sep 2020 16:09:47 |
| User entered '03 Sep 2020 12:09' | System | 03 Sep 2020 16:09:47 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:24', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'None (0)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'None (0)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'None (0)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:44', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'None (0)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:49', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'None (0)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:53', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'None (0)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:07:58', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered 'No (N)' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T12:08:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3418ef96-f388-49cc-a268-6dfc903b0ab7' | System | 28 Aug 2020 16:08:11 |
| User entered '28 Aug 2020 12:08' | System | 28 Aug 2020 16:08:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 11:55' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 14:25' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:03', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' | System | 28 Aug 2020 21:47:36 |
| User entered 'None (0)' | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' | System | 28 Aug 2020 21:47:36 |
| User entered 'None (0)' | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:11', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' | System | 28 Aug 2020 21:47:36 |
| User entered 'None (0)' | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:16', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' User entered 'None (0)' | System | 28 Aug 2020 21:47:36 |
| | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:19', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' | System | 28 Aug 2020 21:47:36 |
| User entered 'None (0)' | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' User entered 'None (0)' | System | 28 Aug 2020 21:47:36 |
| | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:27', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' | System | 28 Aug 2020 21:47:36 |
| User entered 'No (N)' | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-28T17:47:31', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5daab827-e8dd-44b2-be04-d0683203ad1f' | System | 28 Aug 2020 21:47:36 |
| User entered '28 Aug 2020 17:47' | System | 28 Aug 2020 21:47:36 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Aug 2020 15:20' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 2' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered 'None (0)' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:41', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered 'None (0)' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:46', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered 'None (0)' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' User entered 'None (0)' | System | 29 Aug 2020 16:08:19 |
| | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:07:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered 'None (0)' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:08:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered 'None (0)' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:08:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered 'No (N)' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-29T12:08:15', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '67021b7e-0626-4b8a-9650-7eaba192986a' | System | 29 Aug 2020 16:08:19 |
| User entered '29 Aug 2020 12:08' | System | 29 Aug 2020 16:08:19 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 3' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:44', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'None (0)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:48', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'None (0)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:51', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'None (0)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'None (0)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:57', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'None (0)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:44:59', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'None (0)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:45:02', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered 'No (N)' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-30T12:45:06', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b05e0a98-b0ef-4a03-8d91-384e942b82c6' | System | 30 Aug 2020 16:45:28 |
| User entered '30 Aug 2020 12:45' | System | 30 Aug 2020 16:45:28 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '31 Aug 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 4' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered 'None (0)' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:57', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered 'None (0)' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:01:59', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered 'None (0)' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:02:02', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' User entered 'None (0)' | System | 31 Aug 2020 16:03:41 |
| | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:02:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered 'None (0)' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:02:06', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered 'None (0)' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:02:09', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered 'No (N)' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-08-31T12:02:12', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '30bc8d6c-ae0b-48e6-9d82-04145b067c8d' | System | 31 Aug 2020 16:03:41 |
| User entered '31 Aug 2020 12:02' | System | 31 Aug 2020 16:03:41 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '31 Aug 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 5' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:44', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'None (0)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:48', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'None (0)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:05:58', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'None (0)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:06:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'No interference with activity (1)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:06:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'None (0)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:06:10', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'None (0)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:06:14', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered 'No (N)' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-01T12:06:21', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '8dd5678a-a008-44c7-be9a-71e33014c6fc' | System | 01 Sep 2020 16:06:33 |
| User entered '01 Sep 2020 12:06' | System | 01 Sep 2020 16:06:33 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 6' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'None (0)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'None (0)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'None (0)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'No interference with activity (1)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'None (0)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:47', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'None (0)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:51', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered 'No (N)' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-02T12:04:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '223808ca-e0f0-43a4-83c6-975bc0670c6f' | System | 02 Sep 2020 16:05:11 |
| User entered '02 Sep 2020 12:04' | System | 02 Sep 2020 16:05:11 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 7' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:40', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'None (0)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'None (0)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'None (0)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'None (0)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:57', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'None (0)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:09:59', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'None (0)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:10:02', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered 'No (N)' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-03T12:10:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a3df98ef-c12b-4cfe-8b7d-c818b141fe54' | System | 03 Sep 2020 16:10:18 |
| User entered '03 Sep 2020 12:10' | System | 03 Sep 2020 16:10:18 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Sep 2020 12:00' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Sep 2020 11:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Alexandra Arango (b) (4) | 08 Sep 2020 17:06:56 |

US3372284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered '4 Sep 2020' | (b) (4) Alexandra Arango (b) (4) | 08 Sep 2020 17:06:56 |

US3372284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Alexandra Arango (b) (4) | 08 Sep 2020 17:06:56 |

US3372284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Alexandra Arango (b) (4) | 08 Sep 2020 17:06:56 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Alexandra Arango (b) (4) | 08 Sep 2020 17:06:59 |

US3372284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'I' | System | 08 Sep 2020 17:06:59 |

US3372284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Alexandra Arango (b) (4) | 11 Sep 2020 17:09:03 |

US3372284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered '11 Sep 2020' | (b) (4) Alexandra Arango (b) (4) | 11 Sep 2020 17:09:03 |

US3372284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Alexandra Arango (b) (4) | 11 Sep 2020 17:09:03 |

US3372284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Alexandra Arango (b) (4) (b) (4) | 11 Sep 2020 17:09:03 |

US3372284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Alexandra Arango (b) (4) | 11 Sep 2020 17:09:09 |

US3372284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User entered 'I' | System | 11 Sep 2020 17:09:09 |

US3372284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 15:54:51 |

US3372284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered '18 Sep 2020' | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 15:54:51 |

US3372284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 15:54:51 |

US3372284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 15:54:51 |

US3372284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:11:19 |

US3372284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User entered 'I' | System | 28 Sep 2020 17:11:19 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:11:38 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User closed query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 23Oct2020 in PPD Central lab; however Visit 3 is blank in EDC. Please reconcile.' (Site from DM). | (b) (4) | 25 Nov 2020 00:53:35 |
| Query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 23Oct2020 in PPD Central lab; however Visit 3 is blank in EDC. Please reconcile.' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) | 03 Nov 2020 20:41:15 |
| User opened query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 23Oct2020 in PPD Central lab; however Visit 3 is blank in EDC. Please reconcile.' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 21:46:43 |
| User entered '28 Sep 2020' | (b) (4), (b) (6) | 28 Sep 2020 17:11:38 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:11:38 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'VISIT2' | System | 28 Sep 2020 17:11:38 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '28 Sep 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '11:16' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Sep 2020 11:16' | System | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '36.8' C | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Oral (Oral)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '84' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'bpm' | System | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '16' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'breaths/min' | System | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '134' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '78' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 11 Oct 2020 22:52:13 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '28 Sep 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '13:35' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Sep 2020 13:35' | System | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '36.7' C | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Oral (Oral)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '68' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'bpm' | System | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '16' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'breaths/min' | System | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '149' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '87' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'mmHg' | System | 11 Oct 2020 22:53:42 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:53:51 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '28 Sep 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:53:51 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '12:55' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Sep 2020 12:55' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'ONCE' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'INTRAMUSCULAR' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:54:06 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '28 Sep 2020' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:54:06 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:24:17 |
| User entered '12:27' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:54:06 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Sep 2020 12:27' | System | 11 Oct 2020 22:54:06 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered '28 Sep 2020' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered '11:29' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '28 Sep 2020 11:29' | System | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:23:07 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 11 Oct 2020 22:54:21 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:26 |

US3372284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'I' | System | 11 Oct 2020 22:54:26 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:39:51', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd81829fc-9b78-4e63-a30f-05e5396bade5' | System | 28 Sep 2020 17:39:56 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 17:39:56 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:39:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd81829fc-9b78-4e63-a30f-05e5396bade5' | System | 28 Sep 2020 17:39:56 |
| User entered '98.1' | System | 28 Sep 2020 17:39:56 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:40:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd81829fc-9b78-4e63-a30f-05e5396bade5' | System | 28 Sep 2020 17:39:56 |
| User entered 'No (N)' | System | 28 Sep 2020 17:39:56 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:40:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd81829fc-9b78-4e63-a30f-05e5396bade5' | System | 28 Sep 2020 17:39:56 |
| User entered '28 Sep 2020 13:40' | System | 28 Sep 2020 17:39:56 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 13:15' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 15:45' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'ec5972d2-46b0-49d6-a9b4-1dd300361053' | System | 28 Sep 2020 22:11:45 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 22:11:45 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:38', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'ec5972d2-46b0-49d6-a9b4-1dd300361053' | System | 28 Sep 2020 22:11:45 |
| User entered '97.4' | System | 28 Sep 2020 22:11:45 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:41', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'ec5972d2-46b0-49d6-a9b4-1dd300361053' | System | 28 Sep 2020 22:11:45 |
| User entered 'No (N)' | System | 28 Sep 2020 22:11:45 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'ec5972d2-46b0-49d6-a9b4-1dd300361053' | System | 28 Sep 2020 22:11:45 |
| User entered '28 Sep 2020 18:10' | System | 28 Sep 2020 22:11:45 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 16:40' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 2' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:02:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '03cffb6a-31c5-4f4d-87a4-0e05a83187c4' | System | 29 Sep 2020 17:02:46 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 17:02:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:02:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '03cffb6a-31c5-4f4d-87a4-0e05a83187c4' | System | 29 Sep 2020 17:02:46 |
| User entered '97.8' | System | 29 Sep 2020 17:02:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:02:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '03cffb6a-31c5-4f4d-87a4-0e05a83187c4' | System | 29 Sep 2020 17:02:46 |
| User entered 'No (N)' | System | 29 Sep 2020 17:02:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:02:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '03cffb6a-31c5-4f4d-87a4-0e05a83187c4' | System | 29 Sep 2020 17:02:46 |
| User entered '29 Sep 2020 13:02' | System | 29 Sep 2020 17:02:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 3' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:04:18', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '101d9a63-58be-400a-8f60-d3fa601f6ca9' | System | 30 Sep 2020 16:04:30 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 16:04:30 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:04:24', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '101d9a63-58be-400a-8f60-d3fa601f6ca9' | System | 30 Sep 2020 16:04:30 |
| User entered '97.7' | System | 30 Sep 2020 16:04:30 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:04:27', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '101d9a63-58be-400a-8f60-d3fa601f6ca9' | System | 30 Sep 2020 16:04:30 |
| User entered 'No (N)' | System | 30 Sep 2020 16:04:30 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:04:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '101d9a63-58be-400a-8f60-d3fa601f6ca9' | System | 30 Sep 2020 16:04:30 |
| User entered '30 Sep 2020 12:04' | System | 30 Sep 2020 16:04:30 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 4' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:02:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '510f1f74-542c-424b-b0a6-1e0fbcd35702' | System | 01 Oct 2020 16:02:59 |
| User entered 'Yes (Y)' | System | 01 Oct 2020 16:02:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:02:57', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '510f1f74-542c-424b-b0a6-1e0fbcd35702' User entered '97.5' | System | 01 Oct 2020 16:02:59 |
| | System | 01 Oct 2020 16:02:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '510f1f74-542c-424b-b0a6-1e0fbcd35702' | System | 01 Oct 2020 16:02:59 |
| User entered 'No (N)' | System | 01 Oct 2020 16:02:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '510f1f74-542c-424b-b0a6-1e0fbcd35702' | System | 01 Oct 2020 16:02:59 |
| User entered '01 Oct 2020 12:03' | System | 01 Oct 2020 16:02:59 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 5' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:03:26', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '50daba53-3232-49e7-8a91-f1f80bc4989f' | System | 02 Oct 2020 16:03:34 |
| User entered 'Yes (Y)' | System | 02 Oct 2020 16:03:34 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:03:34', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '50daba53-3232-49e7-8a91-f1f80bc4989f' User entered '97.9' | System | 02 Oct 2020 16:03:34 |
| | System | 02 Oct 2020 16:03:34 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:03:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '50daba53-3232-49e7-8a91-f1f80bc4989f' | System | 02 Oct 2020 16:03:34 |
| User entered 'No (N)' | System | 02 Oct 2020 16:03:34 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:03:40', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '50daba53-3232-49e7-8a91-f1f80bc4989f' | System | 02 Oct 2020 16:03:34 |
| User entered '02 Oct 2020 12:03' | System | 02 Oct 2020 16:03:34 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 6' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:26:35', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd228e27d-76db-426d-b8d9-9818e5485c5b' | System | 03 Oct 2020 16:26:40 |
| User entered 'Yes (Y)' | System | 03 Oct 2020 16:26:40 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:26:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd228e27d-76db-426d-b8d9-9818e5485c5b' | System | 03 Oct 2020 16:26:40 |
| User entered '98.4' | System | 03 Oct 2020 16:26:40 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:26:46', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd228e27d-76db-426d-b8d9-9818e5485c5b' | System | 03 Oct 2020 16:26:40 |
| User entered 'No (N)' | System | 03 Oct 2020 16:26:40 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:26:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd228e27d-76db-426d-b8d9-9818e5485c5b' | System | 03 Oct 2020 16:26:40 |
| User entered '03 Oct 2020 12:26' | System | 03 Oct 2020 16:26:40 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 7' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:49:09', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c945dd2c-0e88-41a3-8508-d312f34b325b' | System | 04 Oct 2020 16:49:08 |
| User entered 'Yes (Y)' | System | 04 Oct 2020 16:49:08 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:49:16', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c945dd2c-0e88-41a3-8508-d312f34b325b' User entered '98.7' | System | 04 Oct 2020 16:49:08 |
| | System | 04 Oct 2020 16:49:08 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:49:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c945dd2c-0e88-41a3-8508-d312f34b325b' | System | 04 Oct 2020 16:49:08 |
| User entered 'No (N)' | System | 04 Oct 2020 16:49:08 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:49:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c945dd2c-0e88-41a3-8508-d312f34b325b' | System | 04 Oct 2020 16:49:08 |
| User entered '04 Oct 2020 12:49' | System | 04 Oct 2020 16:49:08 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '41e1493e-ce16-4452-9050-a850992e4183' | System | 28 Sep 2020 17:41:20 |
| User entered 'None (1)' | System | 28 Sep 2020 17:41:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '41e1493e-ce16-4452-9050-a850992e4183' | System | 28 Sep 2020 17:41:20 |
| User entered 'No (N)' | System | 28 Sep 2020 17:41:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '41e1493e-ce16-4452-9050-a850992e4183' | System | 28 Sep 2020 17:41:20 |
| User entered 'No (N)' | System | 28 Sep 2020 17:41:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:25', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '41e1493e-ce16-4452-9050-a850992e4183' | System | 28 Sep 2020 17:41:20 |
| User entered 'None (1)' | System | 28 Sep 2020 17:41:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:30', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '41e1493e-ce16-4452-9050-a850992e4183' | System | 28 Sep 2020 17:41:20 |
| User entered '28 Sep 2020 13:41' | System | 28 Sep 2020 17:41:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 13:15' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 15:45' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:53', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '0e6e880d-0748-431c-a963-cefec8aabb3f' | System | 28 Sep 2020 22:11:48 |
| User entered 'None (1)' | System | 28 Sep 2020 22:11:48 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '0e6e880d-0748-431c-a963-cefec8aabb3f' | System | 28 Sep 2020 22:11:48 |
| User entered 'No (N)' | System | 28 Sep 2020 22:11:48 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:10:58', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '0e6e880d-0748-431c-a963-cefec8aabb3f' | System | 28 Sep 2020 22:11:48 |
| User entered 'No (N)' | System | 28 Sep 2020 22:11:48 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '0e6e880d-0748-431c-a963-cefec8aabb3f' | System | 28 Sep 2020 22:11:48 |
| User entered 'None (1)' | System | 28 Sep 2020 22:11:48 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:10', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '0e6e880d-0748-431c-a963-cefec8aabb3f' User entered '28 Sep 2020 18:11' | System | 28 Sep 2020 22:11:48 |
| | System | 28 Sep 2020 22:11:48 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 16:40' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 2' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:02:51', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '791dcc1f-117c-42dc-84dd-70d61f202102' | System | 29 Sep 2020 17:03:15 |
| User entered 'None (1)' | System | 29 Sep 2020 17:03:15 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:02:58', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '791dcc1f-117c-42dc-84dd-70d61f202102' | System | 29 Sep 2020 17:03:15 |
| User entered 'No (N)' | System | 29 Sep 2020 17:03:15 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:01', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '791dcc1f-117c-42dc-84dd-70d61f202102' | System | 29 Sep 2020 17:03:15 |
| User entered 'No (N)' | System | 29 Sep 2020 17:03:15 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:12', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '791dcc1f-117c-42dc-84dd-70d61f202102' | System | 29 Sep 2020 17:03:15 |
| User entered 'None (1)' | System | 29 Sep 2020 17:03:15 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:18', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '791dcc1f-117c-42dc-84dd-70d61f202102' | System | 29 Sep 2020 17:03:15 |
| User entered '29 Sep 2020 13:03' | System | 29 Sep 2020 17:03:15 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 3' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:04:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a782508e-db24-4779-800d-dfc97315e424' | System | 30 Sep 2020 16:05:12 |
| User entered 'None (1)' | System | 30 Sep 2020 16:05:12 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:01', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a782508e-db24-4779-800d-dfc97315e424' | System | 30 Sep 2020 16:05:12 |
| User entered 'No (N)' | System | 30 Sep 2020 16:05:12 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a782508e-db24-4779-800d-dfc97315e424' | System | 30 Sep 2020 16:05:12 |
| User entered 'No (N)' | System | 30 Sep 2020 16:05:12 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:10', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a782508e-db24-4779-800d-dfc97315e424' | System | 30 Sep 2020 16:05:12 |
| User entered 'None (1)' | System | 30 Sep 2020 16:05:12 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a782508e-db24-4779-800d-dfc97315e424' | System | 30 Sep 2020 16:05:12 |
| User entered '30 Sep 2020 12:05' | System | 30 Sep 2020 16:05:12 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 4' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:15', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e4b3ab0b-8336-4eb5-8487-242f4e64810b' | System | 01 Oct 2020 16:03:36 |
| User entered 'None (1)' | System | 01 Oct 2020 16:03:36 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:21', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e4b3ab0b-8336-4eb5-8487-242f4e64810b' | System | 01 Oct 2020 16:03:36 |
| User entered 'No (N)' | System | 01 Oct 2020 16:03:36 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:24', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e4b3ab0b-8336-4eb5-8487-242f4e64810b' | System | 01 Oct 2020 16:03:36 |
| User entered 'No (N)' | System | 01 Oct 2020 16:03:36 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:35', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e4b3ab0b-8336-4eb5-8487-242f4e64810b' | System | 01 Oct 2020 16:03:36 |
| User entered 'None (1)' | System | 01 Oct 2020 16:03:36 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:40', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e4b3ab0b-8336-4eb5-8487-242f4e64810b' | System | 01 Oct 2020 16:03:36 |
| User entered '01 Oct 2020 12:03' | System | 01 Oct 2020 16:03:36 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 5' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:08', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc922728-127d-4b0c-9c6c-cbbdb5e8cf8' | System | 02 Oct 2020 16:04:20 |
| User entered 'None (1)' | System | 02 Oct 2020 16:04:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc922728-127d-4b0c-9c6c-cbbdb5e8cf8' | System | 02 Oct 2020 16:04:20 |
| User entered 'No (N)' | System | 02 Oct 2020 16:04:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:16', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc922728-127d-4b0c-9c6c-cbbdb5e8cf8' | System | 02 Oct 2020 16:04:20 |
| User entered 'No (N)' | System | 02 Oct 2020 16:04:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:26', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc922728-127d-4b0c-9c6c-cbbdb5e8cf8' | System | 02 Oct 2020 16:04:20 |
| User entered 'None (1)' | System | 02 Oct 2020 16:04:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dc922728-127d-4b0c-9c6c-cbbdb5e8cf8' | System | 02 Oct 2020 16:04:20 |
| User entered '02 Oct 2020 12:04' | System | 02 Oct 2020 16:04:20 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 6' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:27:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c2b86bb-b3ab-46a5-b13c-a7a7f1fe5b9c' | System | 03 Oct 2020 16:27:41 |
| User entered 'None (1)' | System | 03 Oct 2020 16:27:41 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:27:42', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c2b86bb-b3ab-46a5-b13c-a7a7f1fe5b9c' | System | 03 Oct 2020 16:27:41 |
| User entered 'No (N)' | System | 03 Oct 2020 16:27:41 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:27:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c2b86bb-b3ab-46a5-b13c-a7a7f1fe5b9c' | System | 03 Oct 2020 16:27:41 |
| User entered 'No (N)' | System | 03 Oct 2020 16:27:41 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:27:53', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c2b86bb-b3ab-46a5-b13c-a7a7f1fe5b9c' | System | 03 Oct 2020 16:27:41 |
| User entered 'None (1)' | System | 03 Oct 2020 16:27:41 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:27:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c2b86bb-b3ab-46a5-b13c-a7a7f1fe5b9c' | System | 03 Oct 2020 16:27:41 |
| User entered '03 Oct 2020 12:27' | System | 03 Oct 2020 16:27:41 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 7' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:11', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'be2b45b7-9ba4-4bf0-a7f2-0505c8726ee7' | System | 04 Oct 2020 16:50:17 |
| User entered 'None (1)' | System | 04 Oct 2020 16:50:17 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:14', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'be2b45b7-9ba4-4bf0-a7f2-0505c8726ee7' | System | 04 Oct 2020 16:50:17 |
| User entered 'No (N)' | System | 04 Oct 2020 16:50:17 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'be2b45b7-9ba4-4bf0-a7f2-0505c8726ee7' | System | 04 Oct 2020 16:50:17 |
| User entered 'No (N)' | System | 04 Oct 2020 16:50:17 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:28', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'be2b45b7-9ba4-4bf0-a7f2-0505c8726ee7' | System | 04 Oct 2020 16:50:17 |
| User entered 'None (1)' | System | 04 Oct 2020 16:50:17 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:30', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'be2b45b7-9ba4-4bf0-a7f2-0505c8726ee7' | System | 04 Oct 2020 16:50:17 |
| User entered '04 Oct 2020 12:50' | System | 04 Oct 2020 16:50:17 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'None (0)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'None (0)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'None (0)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:49', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'None (0)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:51', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'None (0)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:41:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'None (0)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:42:08', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered 'No (N)' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T13:42:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5cfa7c9c-3b89-4a2a-8c9a-1ed19ac46dc3' | System | 28 Sep 2020 17:42:03 |
| User entered '28 Sep 2020 13:42' | System | 28 Sep 2020 17:42:03 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 13:15' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 15:45' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:15', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'None (0)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:17', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'None (0)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'None (0)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'None (0)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:25', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'None (0)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:27', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'None (0)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:31', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered 'No (N)' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-28T18:11:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '9ea31e03-9261-4a79-a29e-fc1e5f1a0ac0' | System | 28 Sep 2020 22:11:47 |
| User entered '28 Sep 2020 18:11' | System | 28 Sep 2020 22:11:47 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '28 Sep 2020 16:40' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 2' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered 'None (0)' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:26', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered 'None (0)' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered 'None (0)' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' User entered 'None (0)' | System | 29 Sep 2020 17:03:37 |
| | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:34', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered 'None (0)' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered 'None (0)' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:41', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered 'No (N)' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-29T13:03:44', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '5b5ecfa2-c76a-48f7-aef1-96e399ab77a9' | System | 29 Sep 2020 17:03:37 |
| User entered '29 Sep 2020 13:03' | System | 29 Sep 2020 17:03:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 3' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:17', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'None (0)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:20', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'None (0)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'None (0)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:25', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'None (0)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:28', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'None (0)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'None (0)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered 'No (N)' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-09-30T12:05:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd8b8a13e-4786-406b-9aea-8865ff3d59b3' | System | 30 Sep 2020 16:05:29 |
| User entered '30 Sep 2020 12:05' | System | 30 Sep 2020 16:05:29 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 4' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'None (0)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:49', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'None (0)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:51', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'None (0)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:53', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'None (0)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'None (0)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:03:58', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'None (0)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:04:01', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered 'No (N)' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-01T12:04:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '362f1899-1e52-42d1-b756-e52b6b5b09c8' | System | 01 Oct 2020 16:03:54 |
| User entered '01 Oct 2020 12:04' | System | 01 Oct 2020 16:03:54 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 5' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'None (0)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:42', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'None (0)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'None (0)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:48', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'None (0)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'None (0)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered 'No (N)' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-02T12:04:56', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3c0eee8b-20e6-474c-9102-cf2f67632a66' | System | 02 Oct 2020 16:04:46 |
| User entered '02 Oct 2020 12:04' | System | 02 Oct 2020 16:04:46 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 6' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:04', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered 'None (0)' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:15', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered 'None (0)' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:18', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered 'None (0)' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:22', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' User entered 'None (0)' | System | 03 Oct 2020 16:28:21 |
| | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:24', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered 'None (0)' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered 'None (0)' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered 'No (N)' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-03T12:28:35', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'a9e96d1e-6ac5-4258-86a3-50b26abe524e' | System | 03 Oct 2020 16:28:21 |
| User entered '03 Oct 2020 12:28' | System | 03 Oct 2020 16:28:21 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Sep 2020 17:16:09 |
| User entered 'Day 7' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:34', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'None (0)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'None (0)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'None (0)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:41', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'None (0)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'None (0)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:45', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'None (0)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:47', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered 'No (N)' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-04T12:50:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'dfe43d41-3bf6-4baf-8cba-c577adcf8732' | System | 04 Oct 2020 16:50:37 |
| User entered '04 Oct 2020 12:50' | System | 04 Oct 2020 16:50:37 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:16:42

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 17:16:09 |

US3372284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 12 Oct 2020 12:54:02 |

US3372284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 18:25:09 |
| Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | (b) (4), (b) (6) | 13 Nov 2020 16:25:27 |
| answered with 'Per CRA window was based on visit 1 date before new amendment ' (Site from System). | | |
| User entered '02 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Nov 2020 16:24:46 |
| User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 12 Oct 2020 12:54:02 |
| User entered '2 Oct 2020' | Danielle Theodore (b) (4) (b) (4) | 12 Oct 2020 12:54:02 |

US3372284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 12 Oct 2020 12:54:02 |

US3372284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) | 12 Oct 2020 12:54:02 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 12 Oct 2020 12:54:31 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User entered 'I' | System | 12 Oct 2020 12:54:31 |

US3372284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 12 Oct 2020 12:54:53 |

US3372284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 13 Nov 2020 18:25:14 |
| Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | (b) (4), (b) (6) | 13 Nov 2020 16:27:26 |
| answered with 'Per CRA window was based off visit 1 date before new amendment' (Site from System). | | |
| User entered '09 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Nov 2020 16:26:52 |
| User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 12 Oct 2020 12:54:53 |
| User entered '9 Oct 2020' | Danielle Theodore (b) (4) (b) (4) | 12 Oct 2020 12:54:53 |

US3372284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 12 Oct 2020 12:54:53 |

US3372284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) (b) (4) | 12 Oct 2020 12:54:53 |

US3372284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 12 Oct 2020 12:55:21 |

US3372284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User entered 'I' | System | 12 Oct 2020 12:55:21 |

US3372284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 16 Oct 2020 23:39:06 |

US3372284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 17 Nov 2020 11:42:54 |
| Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | (b) (4), (b) (6) | 13 Nov 2020 17:51:19 |
| answered with 'Per CRA window was based off visit 1 date before new amendment' (Site from System). | | |
| User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 16 Oct 2020 23:39:06 |
| User entered '16 Oct 2020' | Danielle Theodore (b) (4) (b) (4) | 16 Oct 2020 23:39:06 |

US3372284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 16 Oct 2020 23:39:06 |

US3372284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) (b) (4) | 16 Oct 2020 23:39:06 |

US3372284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 16 Oct 2020 23:39:15 |

US3372284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:26 |
| User entered 'I' | System | 16 Oct 2020 23:39:15 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:37 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered '23 Oct 2020' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:37 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered 'Clinic (Clinic)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:37 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'VISIT3' | System | 03 Nov 2020 20:40:37 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered empty. | System | 03 Nov 2020 20:40:41 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| | | |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| | | |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:43 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:43 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:50 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered '23 Oct 2020' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:50 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 20:05:02 |
| User entered '11:08' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:50 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered '23 Oct 2020 11:08' | System | 03 Nov 2020 20:40:50 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) | 03 Nov 2020 20:40:58 |

US3372284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'I' | System | 03 Nov 2020 20:40:58 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 64' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-28T12:04:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '45f8cb8f-9db2-46b0-969f-fe083f4d8485' | System | 28 Oct 2020 16:03:51 |
| User entered 'No (N)' | System | 28 Oct 2020 16:03:51 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-28T12:04:18', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '45f8cb8f-9db2-46b0-969f-fe083f4d8485' | System | 28 Oct 2020 16:03:51 |
| User entered 'No (N)' | System | 28 Oct 2020 16:03:51 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-10-28T12:04:26', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '45f8cb8f-9db2-46b0-969f-fe083f4d8485' | System | 28 Oct 2020 16:03:51 |
| User entered '28 Oct 2020 12:04:26' | System | 28 Oct 2020 16:03:51 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered '28 Oct 2020 00:01' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered '01 Nov 2020 23:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 71' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-04T12:03:38', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '20534f26-7467-4ec4-88a6-5b2c305ae1b4' | System | 04 Nov 2020 17:05:50 |
| User entered 'No (N)' | System | 04 Nov 2020 17:05:50 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-04T12:03:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '20534f26-7467-4ec4-88a6-5b2c305ae1b4' | System | 04 Nov 2020 17:05:50 |
| User entered 'No (N)' | System | 04 Nov 2020 17:05:50 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-04T12:03:48', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '20534f26-7467-4ec4-88a6-5b2c305ae1b4' | System | 04 Nov 2020 17:05:50 |
| User entered '04 Nov 2020 12:03:48' | System | 04 Nov 2020 17:05:50 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered '04 Nov 2020 00:01' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered '08 Nov 2020 23:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered 'Day 78' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-11T12:00:44', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '76301d82-db81-465a-8cb9-a801fc1b7114' | System | 11 Nov 2020 17:00:10 |
| User entered 'No (N)' | System | 11 Nov 2020 17:00:10 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-11T12:00:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '76301d82-db81-465a-8cb9-a801fc1b7114' | System | 11 Nov 2020 17:00:10 |
| User entered 'No (N)' | System | 11 Nov 2020 17:00:10 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-11T12:00:54', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '76301d82-db81-465a-8cb9-a801fc1b7114' | System | 11 Nov 2020 17:00:10 |
| User entered '11 Nov 2020 12:00:54' | System | 11 Nov 2020 17:00:10 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered '11 Nov 2020 00:01' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 07:13:57 |
| Data entry locked. | System | 28 Aug 2020 15:42:39 |
| User entered '15 Nov 2020 23:59' | System | 28 Aug 2020 15:42:39 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2020-11-23T10:37:35', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '029a560e-e816-4dcd-8d3a-866a25d92ca8' | System | 23 Nov 2020 15:36:57 |
| User entered 'No (N)' | System | 23 Nov 2020 15:36:57 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2020-11-23T10:37:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '029a560e-e816-4dcd-8d3a-866a25d92ca8' | System | 23 Nov 2020 15:36:57 |
| User entered 'No (N)' | System | 23 Nov 2020 15:36:57 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-23T10:37:53', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '029a560e-e816-4dcd-8d3a-866a25d92ca8' User entered '23 Nov 2020 10:37:53' | System | 23 Nov 2020 15:36:57 |
| | System | 23 Nov 2020 15:36:57 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2020-11-29T13:00:46', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '396fab31-ab40-4f3a-90f1-81f2c2d76f06' | System | 29 Nov 2020 18:00:34 |
| User entered 'Yes (Y)' | System | 29 Nov 2020 18:00:34 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2020-11-29T13:00:53', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '396fab31-ab40-4f3a-90f1-81f2c2d76f06' | System | 29 Nov 2020 18:00:34 |
| User entered 'No (N)' | System | 29 Nov 2020 18:00:34 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-29T13:01:05', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '396fab31-ab40-4f3a-90f1-81f2c2d76f06' | System | 29 Nov 2020 18:00:34 |
| User entered 'No (N)' | System | 29 Nov 2020 18:00:34 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-29T13:01:17', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '396fab31-ab40-4f3a-90f1-81f2c2d76f06' | System | 29 Nov 2020 18:00:34 |
| User entered 'No (N)' | System | 29 Nov 2020 18:00:34 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-11-29T13:01:28', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '396fab31-ab40-4f3a-90f1-81f2c2d76f06' | System | 29 Nov 2020 18:00:34 |
| User entered '29 Nov 2020 13:01:28' | System | 29 Nov 2020 18:00:34 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2020-12-08T17:44:14', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '314498e3-b549-40c5-b4c4-f69cd3015792' | System | 08 Dec 2020 22:43:38 |
| User entered 'No (N)' | System | 08 Dec 2020 22:43:38 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2020-12-08T17:44:23', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '314498e3-b549-40c5-b4c4-f69cd3015792' | System | 08 Dec 2020 22:43:38 |
| User entered 'Yes (Y)' | System | 08 Dec 2020 22:43:38 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-12-08T17:44:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '314498e3-b549-40c5-b4c4-f69cd3015792' | System | 08 Dec 2020 22:43:38 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Dec 2020 22:43:38 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-12-08T17:44:41', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '314498e3-b549-40c5-b4c4-f69cd3015792' | System | 08 Dec 2020 22:43:38 |
| User entered '08 Dec 2020 17:44:41' | System | 08 Dec 2020 22:43:38 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2020-12-13T12:56:57', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '717b1df4-9620-49e9-af6a-12de650b2619' | System | 13 Dec 2020 17:56:01 |
| User entered 'No (N)' | System | 13 Dec 2020 17:56:01 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2020-12-13T12:57:07', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '717b1df4-9620-49e9-af6a-12de650b2619' | System | 13 Dec 2020 17:56:01 |
| User entered 'No (N)' | System | 13 Dec 2020 17:56:01 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-12-13T12:57:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '717b1df4-9620-49e9-af6a-12de650b2619' | System | 13 Dec 2020 17:56:01 |
| User entered '13 Dec 2020 12:57:13' | System | 13 Dec 2020 17:56:01 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2020-12-20T11:03:47', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c18ad961-fbf5-46f9-b055-d1be52dbcaee' | System | 20 Dec 2020 16:02:44 |
| User entered 'No (N)' | System | 20 Dec 2020 16:02:44 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2020-12-20T11:03:52', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c18ad961-fbf5-46f9-b055-d1be52dbcaee' | System | 20 Dec 2020 16:02:44 |
| User entered 'No (N)' | System | 20 Dec 2020 16:02:44 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-12-20T11:03:55', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c18ad961-fbf5-46f9-b055-d1be52dbcaee' | System | 20 Dec 2020 16:02:44 |
| User entered '20 Dec 2020 11:03:55' | System | 20 Dec 2020 16:02:44 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2020-12-27T11:00:25', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '869d6f68-3033-4d96-b219-b7717b0b44e5' | System | 27 Dec 2020 15:59:09 |
| User entered 'No (N)' | System | 27 Dec 2020 15:59:09 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2020-12-27T11:00:29', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '869d6f68-3033-4d96-b219-b7717b0b44e5' | System | 27 Dec 2020 15:59:09 |
| User entered 'No (N)' | System | 27 Dec 2020 15:59:09 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2020-12-27T11:00:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '869d6f68-3033-4d96-b219-b7717b0b44e5' User entered '27 Dec 2020 11:00:33' | System | 27 Dec 2020 15:59:09 |
| | System | 27 Dec 2020 15:59:09 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-01-03T08:09:08', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd29fb405-e17a-46eb-bbde-35447db4a738' | System | 03 Jan 2021 13:07:47 |
| User entered 'No (N)' | System | 03 Jan 2021 13:07:47 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-01-03T08:09:13', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd29fb405-e17a-46eb-bbde-35447db4a738' | System | 03 Jan 2021 13:07:47 |
| User entered 'No (N)' | System | 03 Jan 2021 13:07:47 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-01-03T08:09:19', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd29fb405-e17a-46eb-bbde-35447db4a738' | System | 03 Jan 2021 13:07:47 |
| User entered '03 Jan 2021 08:09:19' | System | 03 Jan 2021 13:07:47 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-01-10T11:06:48', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'aa766ff1-a952-4b1a-ae3c-38ba69f4244d' | System | 10 Jan 2021 16:05:22 |
| User entered 'No (N)' | System | 10 Jan 2021 16:05:22 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-01-10T11:06:52', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'aa766ff1-a952-4b1a-ae3c-38ba69f4244d' | System | 10 Jan 2021 16:05:22 |
| User entered 'No (N)' | System | 10 Jan 2021 16:05:22 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-01-10T11:06:55', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'aa766ff1-a952-4b1a-ae3c-38ba69f4244d' | System | 10 Jan 2021 16:05:22 |
| User entered '10 Jan 2021 11:06:55' | System | 10 Jan 2021 16:05:22 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-01-17T11:00:28', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '574e8aac-8711-4c35-ae7d-b117fdf4610f' | System | 17 Jan 2021 15:58:51 |
| User entered 'No (N)' | System | 17 Jan 2021 15:58:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-01-17T11:00:32', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '574e8aac-8711-4c35-ae7d-b117fdf4610f' | System | 17 Jan 2021 15:58:51 |
| User entered 'No (N)' | System | 17 Jan 2021 15:58:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-01-17T11:00:36', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '574e8aac-8711-4c35-ae7d-b117fdf4610f' User entered '17 Jan 2021 11:00:36' | System | 17 Jan 2021 15:58:51 |
| | System | 17 Jan 2021 15:58:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-01-24T11:01:35', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1bd714fa-263f-4879-adf0-49673eb050d7' | System | 24 Jan 2021 15:59:51 |
| User entered 'No (N)' | System | 24 Jan 2021 15:59:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-01-24T11:01:39', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1bd714fa-263f-4879-adf0-49673eb050d7' | System | 24 Jan 2021 15:59:51 |
| User entered 'No (N)' | System | 24 Jan 2021 15:59:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-01-24T11:01:42', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1bd714fa-263f-4879-adf0-49673eb050d7' | System | 24 Jan 2021 15:59:51 |
| User entered '24 Jan 2021 11:01:42' | System | 24 Jan 2021 15:59:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-01-31T06:26:42', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bf19ebca-e566-42b8-a3e2-8c6abb6a9bfb' | System | 31 Jan 2021 11:24:51 |
| User entered 'No (N)' | System | 31 Jan 2021 11:24:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-01-31T06:26:46', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bf19ebca-e566-42b8-a3e2-8c6abb6a9bfb' | System | 31 Jan 2021 11:24:51 |
| User entered 'No (N)' | System | 31 Jan 2021 11:24:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-01-31T06:26:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'bf19ebca-e566-42b8-a3e2-8c6abb6a9bfb' User entered '31 Jan 2021 06:26:50' | System | 31 Jan 2021 11:24:51 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-02-07T11:05:33', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '6876d47d-6152-4245-a2be-6c8fd5fce2e5' | System | 07 Feb 2021 16:05:44 |
| User entered 'No (N)' | System | 07 Feb 2021 16:05:44 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-02-07T11:05:37', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '6876d47d-6152-4245-a2be-6c8fd5fce2e5' | System | 07 Feb 2021 16:05:44 |
| User entered 'No (N)' | System | 07 Feb 2021 16:05:44 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-02-07T11:05:43', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '6876d47d-6152-4245-a2be-6c8fd5fce2e5' | System | 07 Feb 2021 16:05:44 |
| User entered '07 Feb 2021 11:05:43' | System | 07 Feb 2021 16:05:44 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-02-14T11:00:24', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e2ef152b-2ecc-4fa6-83b1-6e67e6f30440' | System | 14 Feb 2021 16:00:23 |
| User entered 'No (N)' | System | 14 Feb 2021 16:00:23 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-02-14T11:00:27', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e2ef152b-2ecc-4fa6-83b1-6e67e6f30440' | System | 14 Feb 2021 16:00:23 |
| User entered 'No (N)' | System | 14 Feb 2021 16:00:23 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-02-14T11:00:30', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'e2ef152b-2ecc-4fa6-83b1-6e67e6f30440' | System | 14 Feb 2021 16:00:23 |
| User entered '14 Feb 2021 11:00:30' | System | 14 Feb 2021 16:00:23 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-02-21T11:46:44', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '33ed3fb7-996e-43bf-83ac-aebf5c628578' | System | 21 Feb 2021 16:46:37 |
| User entered 'No (N)' | System | 21 Feb 2021 16:46:37 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-02-21T11:46:47', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '33ed3fb7-996e-43bf-83ac-aebf5c628578' | System | 21 Feb 2021 16:46:37 |
| User entered 'No (N)' | System | 21 Feb 2021 16:46:37 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-02-21T11:46:50', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '33ed3fb7-996e-43bf-83ac-aebf5c628578' | System | 21 Feb 2021 16:46:37 |
| User entered '21 Feb 2021 11:46:50' | System | 21 Feb 2021 16:46:37 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-02-28T10:52:49-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3e0a143b-e589-4e87-935d-1b687f048139' User entered 'No (N)' | System | 28 Feb 2021 15:52:36 |
| | System | 28 Feb 2021 15:52:36 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-02-28T10:52:52-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3e0a143b-e589-4e87-935d-1b687f048139' | System | 28 Feb 2021 15:52:36 |
| User entered 'No (N)' | System | 28 Feb 2021 15:52:36 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-02-28T10:52:55-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '3e0a143b-e589-4e87-935d-1b687f048139' | System | 28 Feb 2021 15:52:36 |
| User entered '28 Feb 2021 10:52:55' | System | 28 Feb 2021 15:52:36 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-03-07T11:05:39-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'f462c0de-50c7-40aa-94e9-40ad5cbb788e' | System | 07 Mar 2021 16:06:14 |
| User entered 'No (N)' | System | 07 Mar 2021 16:06:14 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-03-07T11:05:43-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'f462c0de-50c7-40aa-94e9-40ad5cbb788e' | System | 07 Mar 2021 16:06:14 |
| User entered 'No (N)' | System | 07 Mar 2021 16:06:14 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-03-07T11:05:47-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'f462c0de-50c7-40aa-94e9-40ad5cbb788e' User entered '07 Mar 2021 11:05:47' | System | 07 Mar 2021 16:06:14 |
| | System | 07 Mar 2021 16:06:14 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-03-14T10:40:20-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b01207b7-0c89-47d9-9bc2-70c0d2763fd4' | System | 14 Mar 2021 14:39:57 |
| User entered 'No (N)' | System | 14 Mar 2021 14:39:57 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-03-14T10:40:23-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b01207b7-0c89-47d9-9bc2-70c0d2763fd4' | System | 14 Mar 2021 14:39:57 |
| User entered 'No (N)' | System | 14 Mar 2021 14:39:57 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-03-14T10:40:26-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'b01207b7-0c89-47d9-9bc2-70c0d2763fd4' | System | 14 Mar 2021 14:39:57 |
| User entered '14 Mar 2021 10:40:26' | System | 14 Mar 2021 14:39:57 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-03-21T11:00:39-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '51e0bc78-5f5c-4132-bf05-c64a96288f9f' | System | 21 Mar 2021 15:00:17 |
| User entered 'No (N)' | System | 21 Mar 2021 15:00:17 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-03-21T11:00:43-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '51e0bc78-5f5c-4132-bf05-c64a96288f9f' | System | 21 Mar 2021 15:00:17 |
| User entered 'No (N)' | System | 21 Mar 2021 15:00:17 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-03-21T11:00:49-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '51e0bc78-5f5c-4132-bf05-c64a96288f9f' User entered '21 Mar 2021 11:00:49' | System | 21 Mar 2021 15:00:17 |
| | System | 21 Mar 2021 15:00:17 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-03-28T08:05:13-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1be9e75b-3f71-49b1-a66b-6623e57f3d33' | System | 28 Mar 2021 12:04:58 |
| User entered 'No (N)' | System | 28 Mar 2021 12:04:58 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-03-28T08:05:27-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1be9e75b-3f71-49b1-a66b-6623e57f3d33' | System | 28 Mar 2021 12:04:58 |
| User entered 'No (N)' | System | 28 Mar 2021 12:04:58 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-03-28T08:05:32-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1be9e75b-3f71-49b1-a66b-6623e57f3d33' | System | 28 Mar 2021 12:04:58 |
| User entered '28 Mar 2021 08:05:32' | System | 28 Mar 2021 12:04:58 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-04-04T08:49:55-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '777b2e7f-8e60-4a84-8b8f-499a122aee3b' | System | 04 Apr 2021 12:49:36 |
| User entered 'No (N)' | System | 04 Apr 2021 12:49:36 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-04-04T08:49:58-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '777b2e7f-8e60-4a84-8b8f-499a122aee3b' | System | 04 Apr 2021 12:49:36 |
| User entered 'No (N)' | System | 04 Apr 2021 12:49:36 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-04-04T08:50:04-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '777b2e7f-8e60-4a84-8b8f-499a122aee3b' | System | 04 Apr 2021 12:49:36 |
| User entered '04 Apr 2021 08:50:04' | System | 04 Apr 2021 12:49:36 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-04-11T05:58:31-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c45aee0d-b0c9-4dba-99f4-05449c090baf' | System | 11 Apr 2021 09:58:06 |
| User entered 'No (N)' | System | 11 Apr 2021 09:58:06 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-04-11T05:58:37-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c45aee0d-b0c9-4dba-99f4-05449c090baf' | System | 11 Apr 2021 09:58:06 |
| User entered 'No (N)' | System | 11 Apr 2021 09:58:06 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-04-11T05:58:40-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'c45aee0d-b0c9-4dba-99f4-05449c090baf' | System | 11 Apr 2021 09:58:06 |
| User entered '11 Apr 2021 05:58:40' | System | 11 Apr 2021 09:58:06 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-04-18T07:39:02-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '66b2cc23-f36b-4b81-b8d1-357c1da444a2' | System | 18 Apr 2021 11:38:29 |
| User entered 'No (N)' | System | 18 Apr 2021 11:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-04-18T07:39:05-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '66b2cc23-f36b-4b81-b8d1-357c1da444a2' | System | 18 Apr 2021 11:38:29 |
| User entered 'No (N)' | System | 18 Apr 2021 11:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-04-18T07:39:09-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '66b2cc23-f36b-4b81-b8d1-357c1da444a2' | System | 18 Apr 2021 11:38:29 |
| User entered '18 Apr 2021 07:39:09' | System | 18 Apr 2021 11:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-04-25T06:46:38-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f0d2534-bcd0-4e37-b9f9-5315f9119e01' User entered 'No (N)' | System | 25 Apr 2021 10:46:00 |
| | System | 25 Apr 2021 10:46:00 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-04-25T06:46:41-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f0d2534-bcd0-4e37-b9f9-5315f9119e01' | System | 25 Apr 2021 10:46:00 |
| User entered 'No (N)' | System | 25 Apr 2021 10:46:00 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-04-25T06:46:44-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '1f0d2534-bcd0-4e37-b9f9-5315f9119e01' User entered '25 Apr 2021 06:46:44' | System | 25 Apr 2021 10:46:00 |
| | System | 25 Apr 2021 10:46:00 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[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 (42cf3e919f102783)', Time: '2021-05-02T11:00:46-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '158ead5-5dae-4389-bb44-37980640297b' | System | 02 May 2021 15:00:01 |
| User entered 'No (N)' | System | 02 May 2021 15:00:01 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

Have you been exposed to someone with 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 (42cf3e919f102783)', Time: '2021-05-02T11:00:49-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '158eead5-5dae-4389-bb44-37980640297b' | System | 02 May 2021 15:00:01 |
| User entered 'No (N)' | System | 02 May 2021 15:00:01 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-05-02T11:00:52-04:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: '158eead5-5dae-4389-bb44-37980640297b' | System | 02 May 2021 15:00:01 |
| User entered '02 May 2021 11:00:52' | System | 02 May 2021 15:00:01 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '16 Oct 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '20 Oct 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '23 Oct 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '27 Oct 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '30 Oct 2022 00:01' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:16:42

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 19:38:29 |
| Amendment Manager: User entered '03 Nov 2022 23:59' | System | 19 Nov 2020 19:38:29 |

US3372284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:42

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) | 26 Apr 2021 07:02:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-02-28T10:52:39-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd9aed87b-b54e-421d-9a79-24c1a7194dcb' User entered 'No (N)' | System | 28 Feb 2021 15:52:24 |
| | System | 28 Feb 2021 15:52:24 |

US3372284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:16:42

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:02:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42cf3e919f102783)', Time: '2021-02-28T10:52:43-05:00', User OID: 'PatientReportedOutcome (US3372284)', ODM File OID: 'd9aed87b-b54e-421d-9a79-24c1a7194dcb' User entered '28 Feb 2021 10:52:43' | System | 28 Feb 2021 15:52:24 |
| | System | 28 Feb 2021 15:52:24 |

US3372284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 23 Nov 2020 16:19:49 |

US3372284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered '23 Nov 2020' | (b) (4) Danielle Theodore (b) (4) | 23 Nov 2020 16:19:49 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 23 Nov 2020 16:19:49 |

US3372284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) (b) (4) | 23 Nov 2020 16:19:49 |

US3372284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 23 Nov 2020 16:19:58 |

US3372284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 07:24:37 |
| User entered 'I' | System | 23 Nov 2020 16:19:58 |

US3372284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 24 Dec 2020 16:52:03 |

US3372284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered '24 Dec 2020' | (b) (4) Danielle Theodore (b) (4) | 24 Dec 2020 16:52:03 |

US3372284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 24 Dec 2020 16:52:03 |

US3372284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) (b) (4) | 24 Dec 2020 16:52:03 |

US3372284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:01:32 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 24 Dec 2020 16:52:10 |

US3372284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered 'I' | System | 24 Dec 2020 16:52:10 |

US3372284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 26 Jan 2021 18:20:53 |

US3372284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered '26 Jan 2021' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 26 Jan 2021 18:20:53 |

US3372284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 26 Jan 2021 18:20:53 |

US3372284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:38:49 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) (b) (4) | 26 Jan 2021 18:20:53 |

US3372284

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:03:03 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 26 Jan 2021 18:20:59 |

US3372284

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered 'I' | System | 26 Jan 2021 18:20:59 |

US3372284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 23 Feb 2021 22:50:43 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 22 Feb 2021 17:27:37 |

US3372284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 23 Feb 2021 22:50:43 |
| User entered '22 Feb 2021' | (b) (4) Danielle Theodore (b) (4) | 22 Feb 2021 17:27:37 |

US3372284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 23 Feb 2021 22:50:43 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 22 Feb 2021 17:27:37 |
| | (b) (4) | |

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Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 23 Feb 2021 22:50:43 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) (b) (4) | 22 Feb 2021 17:27:37 |

US3372284

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 23 Feb 2021 22:50:43 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 22 Feb 2021 17:29:49 |

US3372284

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered 'I' | System | 22 Feb 2021 17:29:49 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:43 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:43 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:43 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered 'VISIT4' | System | 26 Mar 2021 21:31:43 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| User closed query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 07:14:21 |
| Query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'Data updated.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 19:49:18 |
| Signature has been broken. | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User opened query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" is recorded as "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 05:08:46 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '26 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '11:45' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered empty. | System | 12 Apr 2021 20:12:55 |
| User entered '26 Mar 2021 11:45' | System | 07 Apr 2021 19:48:51 |
| User entered empty. | System | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '36.5' C reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered 'Other (Other)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered 'Forehead' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '84' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered empty. | System | 12 Apr 2021 20:12:55 |
| User entered 'bpm' | System | 07 Apr 2021 19:48:51 |
| User entered empty. | System | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '17' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered empty. | System | 12 Apr 2021 20:12:55 |
| User entered 'breaths/min' | System | 07 Apr 2021 19:48:51 |
| User entered empty. | System | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 12 Apr 2021 21:37:31 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User signature succeeded. | Mira Baron (b) (4) | 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '123' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User signature succeeded. | Mira Baron (b) (4) | 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered empty. | System | 12 Apr 2021 20:12:55 |
| User entered 'mmHg' | System | 07 Apr 2021 19:48:51 |
| User entered empty. | System | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--|--|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User closed query 'Per CDM: Vital Signs: Visit 4 Day 209 and OL-D57 are both dated 26Mar2021. However, data (Diastolic BP) in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify.' (Site from DM). User signature succeeded. | (b) (4), (b) (6) Mira Baron (b) (4) | 13 Apr 2021 06:04:24 12 Apr 2021 21:37:31 |
| Query 'Per CDM: Vital Signs: Visit 4 Day 209 and OL-D57 are both dated 26Mar2021. However, data (Diastolic BP) in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify.' answered with 'Data updated.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 20:13:41 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 20:12:55 |
| User opened query 'Per CDM: Vital Signs: Visit 4 Day 209 and OL-D57 are both dated 26Mar2021. However, data (Diastolic BP) in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify.' (Site from DM). User signature succeeded. | (b) (4), (b) (6) Mira Baron (b) (4) | 11 Apr 2021 08:14:49 08 Apr 2021 16:45:03 |
| Signature has been broken. | (b) (4), (b) (6) | 07 Apr 2021 19:48:51 |
| User entered '76' reason for change: Data Entry Error User signature succeeded. | (b) (4), (b) (6) Mira Baron (b) (4) | 07 Apr 2021 19:48:51 05 Apr 2021 13:21:53 |
| User entered empty. | (b) (4), (b) (6) | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered empty. | System | 12 Apr 2021 20:12:55 |
| User entered 'mmHg' | System | 07 Apr 2021 19:48:51 |
| User entered empty. | System | 02 Apr 2021 19:03:48 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| | | |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| | | |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:49 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:49 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:58 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:58 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '11:58' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:31:58 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered '26 Mar 2021 11:58' | System | 26 Mar 2021 21:31:58 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:02 |

US3372284

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 11:52:46 |
| User entered 'I' | System | 26 Mar 2021 21:32:02 |

US3372284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 27 Apr 2021 01:41:13 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Danielle Theodore (b) (4) | 26 Apr 2021 15:20:04 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 27 Apr 2021 01:41:13 |
| | (b) (4) | |
| User entered '26 Apr 2021' | Danielle Theodore (b) (4) | 26 Apr 2021 15:20:04 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 27 Apr 2021 01:41:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 26 Apr 2021 15:20:04 |

US3372284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 27 Apr 2021 01:41:13 |
| User entered empty. | (b) (4) | |
| | Danielle Theodore (b) (4) | 26 Apr 2021 15:20:04 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 27 Apr 2021 01:41:13 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Danielle Theodore (b) (4) | 26 Apr 2021 15:20:11 |
| | (b) (4) | |

US3372284

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Apr 2021 15:20:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:43 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:41 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:01:42 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:43 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:41 |
| User entered '08:29' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:01:42 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:43 |
| User entered '03 Dec 2020 08:29' | System | 07 Dec 2020 21:01:42 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:43 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:41 |
| User entered 'Safety Call (Safety Call)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:01:42 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:43 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:41 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:01:42 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 1 (Day 1)' | (b) (4) Jennifer Torres (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User closed query 'Per ETRTR: Please consider that if onset of Symptoms was 30Nov20, COVID-19 AE page should have Start date as 30Nov20 instead of 03Dec20, thanks.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 19:59:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 19:59:10 |
| Query 'Per ETRTR: Please consider that if onset of Symptoms was 30Nov20, COVID-19 AE page should have Start date as 30Nov20 instead of 03Dec20, thanks.' answered with 'data correct as is' (Site from CRA). | (b) (4), (b) (6) | 07 Feb 2021 22:19:29 |
| User opened query 'Per ETRTR: Please consider that if onset of Symptoms was 30Nov20, COVID-19 AE page should have Start date as 30Nov20 instead of 03Dec20, thanks.' (Site from CRA). | (b) (4), (b) (6) | 21 Dec 2020 16:26:09 |
| User entered '30 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:33 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:34 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:36 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:31 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:27 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:28 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:25 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:22 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:21 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:20 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:14 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:13 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:11 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:51:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:03:56 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 2 (Day 2)' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:15 |
| User entered '01 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:16 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:17 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:19 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:20 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:25 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:27 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:28 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:32 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:33 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:35 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:39 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:43 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:44 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:45 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:47 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:53:48 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:05:55 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 3 (Day 3)' | (b) (4) Jennifer Torres (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:24 |
| User entered '02 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:25 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:26 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:29 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:32 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:33 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:34 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:35 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:37 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:40 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:44 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:46 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:47 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:48 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:50 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:52 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:53 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:54:55 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:06:47 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 4 (Day 4)' reason for change: | (b) (4) | |
| Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:08:33 |
| User entered 'Day 3 (Day 3)' | (b) (4) | |
| | Jennifer Torres (b) (4) | 07 Dec 2020 21:08:18 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 21:09:18 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered '03 Dec 2020' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 21:09:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered '0' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 21:09:21 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered '96' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 21:09:22 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered '97.5' F | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:29 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Dec 2020 18:56:49 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) | 07 Dec 2020 21:08:18 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:21 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:11 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:13 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:14 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:56:54 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:56:58 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:01 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:57:00 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 5 (Day 5)' reason for change: | (b) (4) | |
| Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) | |
| | Jennifer Torres (b) (4) | 07 Dec 2020 21:08:33 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:01 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Dec 2020 21:10:13 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Dec 2020 21:10:13 |
| User entered '04 Dec 2020' reason for change: Data Entry Error | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:10:13 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Dec 2020 21:08:33 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:02 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:58:59 |
| User entered '97' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:10:13 |
| User entered empty. | System | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:58:58 |
| User entered '99.3' F reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:58 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:30 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:52 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:54 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:55 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:51 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:50 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:47 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:46 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:43 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:41 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:40 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:38 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

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Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:37 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:36 |
| User entered 'None (None)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:59:34 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Jennifer Torres (b) (4) | 07 Dec 2020 21:10:13 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:08:33 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 6 (Day 6)' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:06 |
| User entered '05 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:07 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:00:58 |
| User entered '97' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:04 |
| User entered '99.9' F | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:58 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:28 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:57 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:55 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:54 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:52 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:49 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:46 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:44 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:43 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:34 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:33 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:42 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:40 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:01:36 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:11:52 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 7 (Day 7)' | (b) (4) Jennifer Torres (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:02:58 |
| User entered '06 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:00 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:01 |
| User entered '97' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:03 |
| User entered '99.9' F | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:05 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:11 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:14 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:22 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:20 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:23 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:27 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:03:28 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:12:58 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 8 (Day 8)' | (b) (4) Jennifer Torres (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:09 |
| User entered '07 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:10 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:11 |
| User entered '96' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:13 |
| User entered '99.0' F | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:14 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:07 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:50 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:49 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:47 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:46 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:45 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:34 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:32 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:40 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:37 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 19:05:35 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:14:49 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 9 (Day 9)' | (b) (4) Jennifer Torres (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:31 |
| User entered '08 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:32 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:34 |
| User entered '97' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:35 |
| User entered '98.8' F | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:37 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:38 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:43 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:45 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:47 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:49 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:50 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 13:32:35 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'None (None)' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:55 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:56 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:12:58 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:13:00 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:13:01 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:13:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:13:05 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:16:46 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 10 (Day 10)' | (b) (4) Jennifer Torres (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:41 |
| User entered '09 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:43 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:44 |
| User entered '94' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:45 |
| User entered '97.8' F | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:47 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:52 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:53 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:55 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:57 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:14:59 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:00 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:10 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:12 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:15:20 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:23:24 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 11 (Day 11)' | Jennifer Torres (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:47 |
| User entered '10 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:45 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:38 |
| User entered '98' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:39 |
| User entered '96.9' F | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:48 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:49 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:52 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:53 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:54 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:56 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:57 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:58 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:16:59 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:01 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:03 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:05 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:17:11 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:27:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 12 (Day 12)' | Jennifer Torres (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:02 |
| User entered '11 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:04 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:05 |
| User entered '95' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:07 |
| User entered '97.6' F | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:09 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:19 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:21 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:22 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:25 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:28 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:29 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:32 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:18:33 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:36:14 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 13 (Day 13)' | (b) (4) Jennifer Torres (b) (4) | 14 Dec 2020 15:37:04 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:45 |
| User entered '12 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:47 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:40 |
| User entered '98' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:41 |
| User entered '97.6' F | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:43 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:42 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:50 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:51 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:52 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:53 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:55 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:57 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:19:59 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:00 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:03 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:06 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:09 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:20:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:37:04 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 14 (Day 14)' | Jennifer Torres (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:13 |
| User entered '13 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:14 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:11 |
| User entered '96' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:10 |
| User entered '97.9' F | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:18 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:19 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:23 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:26 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:28 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:29 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:31 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:33 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:36 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:37 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:39 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:21:42 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:41:16 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 15 (Day 15)' | (b) (4) Jennifer Torres (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:39 |
| User entered '14 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:40 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:38 |
| User entered '98' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:36 |
| User entered '97.5' F | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:43 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:44 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:47 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:48 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:50 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:51 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:53 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:54 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:56 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:22:59 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:01 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:06 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:48:31 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 16 (Day 16)' | Jennifer Torres (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User closed query 'Please verify if the entries noted after this visit in the source should be entered.' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 21:10:42 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| Query 'Please verify if the entries noted after this visit in the source should be entered.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) | 15 Feb 2021 22:19:07 |
| User opened query 'Please verify if the entries noted after this visit in the source should be entered.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 20:25:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 20:23:56 |
| User entered '15 Dec 2020' | Jennifer Torres (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:57 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:54 |
| User entered '98' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:23:53 |
| User entered '99.0' F | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:01 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:02 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:03 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:05 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:09 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:13 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:19 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:20 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 20:24:25 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 16 Dec 2020 17:49:29 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 17 (Day 17)' | (b) (4) Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:10:54 |
| User entered '16 Dec 2020' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:10:55 |
| User entered '0' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:10:52 |
| User entered '96' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:10:57 |
| User entered '98.6' F | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:10:58 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:09 |
| User entered 'Mild (Mild)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:11 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:12 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:14 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:54 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:55 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:57 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:11:59 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:01 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:03 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | 03 Feb 2021 17:12:05 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Dec 2020 21:14:06 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:06 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:08 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:13 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:15 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:14:06 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 18 (Day 18)' | (b) (4) Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:49 |
| User entered '17 Dec 2020' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:53 |
| User entered '0' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:50 |
| User entered '96' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:52 |
| User entered '97.6' F | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:56 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:12:58 |
| User entered 'Mild (Mild)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:06 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:07 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:09 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:10 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:12 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:13 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:15 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:16 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:19 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:21 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 17:13:23 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | 03 Feb 2021 17:13:24 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Dec 2020 21:15:03 |
| | Mary Sergalis (b) (4) | |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:26 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:13:28 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:15:03 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 19 (Day 19)' | (b) (4) Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User closed query 'Please complete Day 21 and 28 CRF entries as noted in source.' (Site from CRA). | (b) (4), (b) (6) | 26 Feb 2021 18:54:58 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| Query 'Please complete Day 21 and 28 CRF entries as noted in source.' answered with 'data updated' (Site from CRA). | (b) (4) | |
| | Peter Jacob (b) (4) | 15 Feb 2021 22:18:58 |
| | (b) (4) | |
| User opened query 'Please complete Day 21 and 28 CRF entries as noted in source.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 17:17:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 17:14:05 |
| User entered '18 Dec 2020' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:10 |
| User entered '0' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:07 |
| User entered '96' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User entered '%' | System | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:08 |
| User entered '97.8' F | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:13 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 17:14:15 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:17 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:18 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | 03 Feb 2021 17:14:20 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Dec 2020 21:16:11 |
| | Mary Sergalis (b) (4) | |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:21 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:23 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:26 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:28 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:29 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:32 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:33 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | 03 Feb 2021 17:14:35 |
| User entered 'None (None)' | (b) (4), (b) (6) | 30 Dec 2020 21:16:11 |
| | | |
| | | |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:37 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:38 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:14:40 |
| User entered 'None (None)' | Mary Sergalis (b) (4) | 30 Dec 2020 21:16:11 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | (b) (4), (b) (6) | 14 Dec 2020 19:51:52 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'UPDATED' (Site from System). | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:12:37 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Dec 2020 21:15:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Dec 2020 21:15:41 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | System | 07 Dec 2020 21:15:41 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:15:41 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Dec 2020 21:02:18 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:10:55 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:02:18 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:07 |
| User entered 'I' | System | 07 Dec 2020 21:15:41 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

Did the subject have Respiratory Rates \geq 30 per Minute?

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

Did the subject have Heart Rate \geq 125 beats per minute

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
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[Oxygen Saturation](#)

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[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

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[PaO2](#)

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[Did the subject have Respiratory failure?](#)

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

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[High-Flow Oxygen?](#)

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[Non-Invasive Ventilation?](#)

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[Mechanical Ventilation?](#)

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[ECMO?](#)

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[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

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[Evidence of Shock Requires
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Radiographical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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Generated On: 09 Jun 2021 17:16:42

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 03 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:16:42

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:45:11 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 16:11:11 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 15:58:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 13:26:44 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| User entered '16 Nov 2020' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 13:26:48 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| User entered '09:10' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:24 |
| User entered '16 Nov 2020 09:10' | System | 18 Nov 2020 15:28:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 13:26:51 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| User entered 'Safety Call (Safety Call)' | Jennifer Torres (b) (4) | 18 Nov 2020 15:28:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:16:42

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 14:40:43 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:03:57 |
| User entered 'Yes (Y)' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 1 (Day 1)' | (b) (4) Jennifer Torres (b) (4) | 19 Nov 2020 15:16:29 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:37 |
| User entered '14 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:35 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:22 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:24 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:26 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:28 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:32 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:13 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:14 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:09 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:05 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:03 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:00 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 14:33:45 |
| User closed query 'Please verify, not noted in source on this day.' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 14:33:39 |
| Query 'Please verify, not noted in source on this day.' answered with 'it is noted in source on this day' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:49:52 |
| User opened query 'Please verify, not noted in source on this day.' (Site from CRA). | (b) (4), (b) (6) | 14 Jan 2021 14:40:22 |
| User closed query 'Please verify, noted as started 15Nov2020 in source.' (Site from CRA). | (b) (4), (b) (6) | 14 Jan 2021 14:40:22 |
| Query 'Please verify, noted as started 15Nov2020 in source.' answered with 'data updated' (Site from CRA). | (b) (4), (b) (6) | 05 Jan 2021 20:00:01 |
| User opened query 'Please verify, noted as started 15Nov2020 in source.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 18:06:57 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:16:29 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 2 (Day 2)' | (b) (4) Jennifer Torres (b) (4) | 19 Nov 2020 15:17:04 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:49 |
| User entered '15 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:48 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:51 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:52 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:54 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:56 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:57 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:07:59 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:02 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:05 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:07 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:21 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:19 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:08:18 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:04 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 3 (Day 3)' | (b) (4) Jennifer Torres (b) (4) | 19 Nov 2020 15:17:55 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:02 |
| User entered '16 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:03 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:23 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:24 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:25 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:22 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:31 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:28 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:34 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:33 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:36 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:09:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:10:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:10:39 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:10:37 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:10:35 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:10:33 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:10:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

Sore Throat

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 01 Apr 2021 12:40:01 |
| User closed query 'According to eMR, AE 'Sore Throat' start date is 15Nov2020 end date is 17Nov2020. Please, review and reconcile or clarify. Thank you,(b) (6) (Site from CRA). | (b) (4), (b) (6) | 31 Mar 2021 14:56:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 14:56:09 |
| Query 'According to eMR, AE 'Sore Throat' start date is 15Nov2020 end date is 17Nov2020. Please, review and reconcile or clarify. Thank you,(b) (6) answered with 'Data updated ' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 15:22:20 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Mar 2021 15:22:09 |
| Signature has been broken. | (b) (4), (b) (6) | 19 Mar 2021 15:22:09 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 15:22:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:12:31 |
| User opened query 'According to eMR, AE 'Sore Throat' start date is 15Nov2020 end date is 17Nov2020. Please, review and reconcile or clarify. Thank you,(b) (6) (Site from CRA). | (b) (4), (b) (6) | 16 Mar 2021 20:12:29 |
| User closed query 'Please verify, noted as continuing on this day, stopped 17Nov2020.' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 16:16:59 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| Query 'Please verify, noted as continuing on this day, stopped 17Nov2020.' answered with 'data correct as is' (Site from CRA). | Peter Jacob (b) (4) | 19 Jan 2021 16:50:48 |
| User opened query 'Please verify, noted as continuing on this day, stopped 17Nov2020.' (Site from CRA). | (b) (4), (b) (6) | 14 Jan 2021 14:41:46 |
| User closed query 'Please verify, noted as ongoing in source on this date.' (Site from CRA). | (b) (4), (b) (6) | 14 Jan 2021 14:41:46 |
| Query 'Please verify, noted as ongoing in source on this date.' answered with 'data updated' (Site from CRA). | (b) (4), (b) (6) | 05 Jan 2021 19:59:49 |
| User opened query 'Please verify, noted as ongoing in source on this date.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 18:10:28 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:17:55 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 4 (Day 4)' | (b) (4) Jennifer Torres (b) (4) | 19 Nov 2020 15:19:28 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:08 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:09 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:12 |
| User entered '96' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:13 |
| User entered '97.7' F | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:17 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:22 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:14 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:04 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:13:01 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:58 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:57 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:56 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:55 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:12:53 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:19:28 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 5 (Day 5)' | (b) (4) Jennifer Torres (b) (4) | 19 Nov 2020 15:22:19 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:06 |
| User entered '18 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:04 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:02 |
| User entered '96' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:03 |
| User entered '97.7' F | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:09 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:08 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:10 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:13 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:17 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:29 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:27 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:25 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:22 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:21 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:14:33 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:22:19 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 6 (Day 6)' | Jennifer Torres (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:03 |
| User entered '19 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:04 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:01 |
| User entered '94' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:00 |
| User entered '98.0' F | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:05 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:07 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:08 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:11 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:12 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:15 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:16 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:18 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:19 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:20 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:24 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:25 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:27 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:28 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:30 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:15:31 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:05 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| User entered 'Day 7 (Day 7)' | (b) (4) Jennifer Torres (b) (4) | 24 Nov 2020 14:36:51 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:07 |
| User entered '20 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:10 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:08 |
| User entered '96' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User entered '%' | System | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:11 |
| User entered '97.8' F | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:13 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:32 |
| User entered 'Mild (Mild)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:31 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:35 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:36 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:38 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:39 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:41 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:43 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:44 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:45 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:48 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:49 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Dec 2020 18:16:51 |
| User entered 'None (None)' | Jennifer Torres (b) (4) | 24 Nov 2020 14:36:51 |
| | (b) (4) | |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:52 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:16:42

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:30 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:55:18 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:16:54 |
| User entered 'None (None)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:36:51 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | (b) (4), (b) (6) | 14 Dec 2020 19:51:24 |
| User entered 'No (N)' reason for change: Data Entry Error | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:11:29 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE WILL BE UPDATED' (Site from System). | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:07:48 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 12 Dec 2020 00:07:25 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Dec 2020 00:07:25 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). | System | 12 Dec 2020 00:07:25 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:07:25 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 18 Nov 2020 15:28:59 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:01:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:06 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:28:59 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:16:42

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:34 |
| User entered '0' | System | 12 Dec 2020 00:11:29 |
| User entered '1' | System | 12 Dec 2020 00:07:25 |

US3372284

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:16:42

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 17:44:38 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:59:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:59:38 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:29:07 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:58:11 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:58:13 |
| User entered '19 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 24 Feb 2021 18:53:51 |
| User closed query 'Please verify, saliva collection completed through Day 28 per lab reports.' (Site from CRA). | (b) (4), (b) (6) | 24 Feb 2021 18:53:49 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Query 'Please verify, saliva collection completed through Day 28 per lab reports.' answered with 'data correct as is' (Site from CRA). | Peter Jacob (b) (4) | 15 Feb 2021 22:20:23 |
| User opened query 'Please verify, saliva collection completed through Day 28 per lab reports.' (Site from CRA). | (b) (4), (b) (6) | 08 Jan 2021 18:53:00 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 24 Feb 2021 18:53:53 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered empty. | (b) (4) | |
| | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:22:50 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered 'No (N)' | (b) (4) Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:22:51 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:22:59 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:01 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:05 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:07 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:11 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered 'No (N)' | (b) (4) | |
| | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:13 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered empty. | (b) (4) Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Jennifer Torres (b) (4) (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:17 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered 'No (N)' | (b) (4) | |
| | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Mar 2021 20:23:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered empty. | Jennifer Torres (b) (4) | 24 Nov 2020 14:37:29 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 15:52:31 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 15:52:33 |
| User entered '05 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 15:53:28 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 15:53:26 |
| User entered '07 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 15:54:07 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 15:54:05 |
| User entered '09 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 15:53:46 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 16DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 06:50:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Jan 2021 15:53:47 |
| Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 16DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'data correct as is' (Site from DM). | (b) (4), (b) (6) | 05 Jan 2021 16:03:03 |
| User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 16DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 24 Dec 2020 08:34:50 |
| User entered '11 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Jan 2021 15:54:49 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 16:03:42 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 14 Dec 2020 16:01:41 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 18 Jan 2021 15:54:50 |
| User entered '16 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 16:03:42 |
| User entered empty. | Jennifer Torres (b) (4) | 14 Dec 2020 16:01:41 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Feb 2021 18:05:21 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 16:04:06 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 14 Dec 2020 16:01:41 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Per GCL Lab Recon: Saliva: Sample dated 30 DEC 2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Feb 2021 09:23:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Query 'Per GCL Lab Recon: Saliva: Sample dated 30 DEC 2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) | 15 Feb 2021 22:18:38 |
| User opened query 'Per GCL Lab Recon: Saliva: Sample dated 30 DEC 2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM). | (b) (4), (b) (6) | 09 Feb 2021 16:11:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Feb 2021 18:05:21 |
| User entered '23 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 16:04:06 |
| User entered empty. | Jennifer Torres (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:16:42

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Jennifer Torres (b) (4) (b) (4) | 14 Dec 2020 16:01:41 |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:16:42

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Please verify, noted as collected 30Dec2020 and results are in Preclarus.' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 16:18:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:18:47 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Query 'Please verify, noted as collected 30Dec2020 and results are in Preclarus.' answered with 'data updated' (Site from CRA). | (b) (4) | |
| | Peter Jacob (b) (4) | 15 Feb 2021 22:18:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:18:19 |
| | (b) (4) | |
| User opened query 'Please verify, noted as collected 30Dec2020 and results are in Preclarus.' (Site from CRA). | (b) (4), (b) (6) | 15 Feb 2021 17:19:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 15 Feb 2021 17:18:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Feb 2021 18:05:21 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 14 Dec 2020 16:01:41 |
| | (b) (4) | |

US3372284

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:18:49 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered '30 Dec 2020' reason for change: Data Entry Error | (b) (4) | |
| | Peter Jacob (b) (4) | 15 Feb 2021 22:18:19 |
| DataPoint Un-verified. | (b) (4) | |
| | (b) (4), (b) (6) | 15 Feb 2021 17:18:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Feb 2021 18:05:21 |
| User entered empty. | Jennifer Torres (b) (4) | 14 Dec 2020 16:01:41 |
| | (b) (4) | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the sample SARS-CoV-2 serum has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 14:32:21 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the sample SARS-CoV-2 serum has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:22:57 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the sample SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:22:44 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 30 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the sample SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:21:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 17:49:37 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:29:54 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:49:37 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:29:54 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:49:37 |
| User entered 'Clinic (Clinic)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:29:54 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'SICKD1' | System | 18 Nov 2020 15:29:54 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered '11:10' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered '17 Nov 2020 11:10' | System | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered '65' in | Jennifer Torres (b) (4) | 18 Nov 2020 15:31:50 |
| DataPoint set to visible. | (b) (4) System | 18 Nov 2020 15:29:54 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) | 18 Nov 2020 15:31:50 |
| DataPoint set to visible. | (b) (4) System | 18 Nov 2020 15:29:54 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered '97.7' F | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered 'Other (Other)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered 'FOREHEAD' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User closed query 'Pulse reported is out of range < 45 System or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 18 Nov 2020 15:32:07 |
| Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 18 Nov 2020 15:32:07 |
| User entered '97' reason for change: Data Entry Error | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:32:07 |
| User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 18 Nov 2020 15:31:50 |
| User entered '17' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'bpm' | System | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 18 Nov 2020 15:32:07 |
| Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 18 Nov 2020 15:32:07 |
| User entered '17' reason for change: Data Entry Error | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:32:07 |
| User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 18 Nov 2020 15:31:50 |
| User entered '97' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'breaths/min' | System | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered '150' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'mmHg' | System | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:21 |
| User entered '95' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'mmHg' | System | 18 Nov 2020 15:31:50 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| | | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| | | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:29 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:32:21 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:51:29 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:32:21 |

US3372284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:14:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 17:57:02 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Dec 2020 17:53:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 17:53:00 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:32:28 |

US3372284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:14:01 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 30 DEC 2020 is reported under Convalescent Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC by entering data in Convalescence visit day 28 form for SARS sample dated 30 DEC 2020 or provide clarification for missing sample data in EDC. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 14:32:11 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 30 DEC 2020 is reported under Convalescent Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC by entering data in Convalescence visit day 28 form for SARS sample dated 30 DEC 2020 or provide clarification for missing sample data in EDC. Thank you.' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:56:07 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 sample: Sample dated 30 DEC 2020 is reported under Convalescent Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the SARS sample details in EDC by entering data in Convalescence visit day 28 form for SARS sample dated 30 DEC 2020 or provide clarification for missing sample data in EDC. Thank you.' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 15:10:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 17:57:02 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Dec 2020 17:53:08 |

US3372284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 17:53:00 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 18 Nov 2020 15:32:28 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:37:13 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:13:30 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:37:13 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:13:30 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:37:13 |
| User entered 'Home (Home)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:13:30 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'SICKD1' | System | 07 Dec 2020 21:13:30 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:55 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:54 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:45:27 |
| User entered '11:35' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered '03 Dec 2020 11:35' | System | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:52 |
| User entered missing code ND - Not Done. | Jennifer Torres (b) (4) | 07 Dec 2020 21:14:34 |
| DataPoint set to visible. | (b) (4) System | 07 Dec 2020 21:13:30 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:40:47 |
| User entered '313.6' lb | Jennifer Torres (b) (4) | 07 Dec 2020 21:14:34 |
| DataPoint set to visible. | (b) (4) System | 07 Dec 2020 21:13:30 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:17 |
| User entered '97.5' F | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 19:35:06 |
| User closed query 'Please verify, noted as forehead in source.' (Site from CRA). | (b) (4), (b) (6) | 30 Dec 2020 19:35:01 |
| Query 'Please verify, noted as forehead in source.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 15:09:59 |
| User entered 'Other (Other)' reason for change: Data Entry Error | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 15:06:37 |
| User opened query 'Please verify, noted as forehead in source.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 21:40:34 |
| User entered 'Oral (Oral)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 19:35:04 |
| DataPoint Un-verified. | Peter Jacob (b) (4) | 23 Dec 2020 15:06:37 |
| User entered 'forehead' reason for change: Data Entry Error | (b) (4) Peter Jacob (b) (4) | 23 Dec 2020 15:06:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:39 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:38 |
| User entered '94' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'bpm' | System | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:37 |
| User entered '19' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'breaths/min' | System | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:31 |
| User entered '150' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'mmHg' | System | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:39:33 |
| User entered '80' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User entered 'mmHg' | System | 07 Dec 2020 21:14:34 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| | | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| | | |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:45:58 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:44 |

US3372284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:45:58 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:44 |

US3372284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:14:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:46:05 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:52 |

US3372284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:49:06 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:14:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 21:46:05 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) (b) (4) | 07 Dec 2020 21:14:52 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:13 |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:53:48 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:13 |
| User entered '30 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:53:48 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:13 |
| User entered 'Clinic (Clinic)' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:53:48 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User entered 'SICKD28' | System | 19 Jan 2021 16:53:48 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:38 |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:39 |
| User entered '30 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:41 |
| User entered '09:11' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User entered '30 Dec 2020 09:11' | System | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:50 |
| User entered '36' C | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:54 |
| User entered 'Other (Other)' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:52 |
| User entered 'forehead' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:55 |
| User entered '89' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User entered 'bpm' | System | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:06:57 |
| User entered '16' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User entered 'breaths/min' | System | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:07:28 |
| User entered '148' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User entered 'mmHg' | System | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 26 Mar 2021 21:04:38 |
| Signature has been broken indirectly. | (b) (4) | 26 Mar 2021 21:01:12 |
| User signature succeeded. | System | 26 Mar 2021 21:01:12 |
| | Mira Baron (b) (4) | 17 Feb 2021 03:33:17 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Feb 2021 18:07:26 |
| User entered '93' | Peter Jacob (b) (4) | 19 Jan 2021 16:55:25 |
| | (b) (4) | |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User entered 'mmHg' | System | 19 Jan 2021 16:55:25 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| | | |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| | | |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:07:46 |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:36 |

US3372284

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:07:44 |
| User entered '30 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:36 |

US3372284

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:14:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:10:00 |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:51 |

US3372284

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:16:42

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:46:10 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:14:01 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:10:02 |
| User entered '30 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 19 Jan 2021 16:55:51 |

US3372284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:16 |

US3372284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:16 |

US3372284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:17:01 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:16 |

US3372284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'UNBLND_DECIDE' | System | 28 Jan 2021 18:38:16 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 14:11:54 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 14:11:54 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:01:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '1' | System | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:16:42

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'I' | System | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered empty. | System | 28 Jan 2021 18:48:24 |
| DataPoint set to visible. | System | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered empty. | System | 28 Jan 2021 18:48:24 |
| DataPoint set to visible. | System | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '09:05' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '28 Jan 2021 09:05' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '36.5' C | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Other (Other)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'FOREHEAD' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '71' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'bpm' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '20' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'breaths/min' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '134' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:16:42

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered empty. | System | 28 Jan 2021 18:48:24 |
| DataPoint set to visible. | System | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '10:30' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '28 Jan 2021 10:30' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '36.4' C | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'Other (Other)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered 'FOREHEAD' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'bpm' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '20' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'breaths/min' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '135' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 03:49:37 |
| User entered '90' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 28 Jan 2021 18:48:24 |

US3372284

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:29 |

US3372284

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:11:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:29 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

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) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mRNA-1273' | System | 28 Jan 2021 18:48:44 |
| DataPoint set to visible. | System | 28 Jan 2021 18:38:33 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered '09:57' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '28 Jan 2021 09:57' | System | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 23:47:10 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'ONCE' | System | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'INTRAMUSCULAR' | System | 28 Jan 2021 18:48:44 |

US3372284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:06:54 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:44 |

US3372284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:06:54 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:44 |

US3372284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 00:06:54 |
| User entered '08:49' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:38:44 |

US3372284

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '28 Jan 2021 08:49' | System | 28 Jan 2021 18:38:44 |

US3372284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:42:04 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:39:01 |

US3372284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:42:04 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:39:01 |

US3372284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 17:42:04 |
| User entered '08:40' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:39:01 |

US3372284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:16:42

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '28 Jan 2021 08:40' | System | 28 Jan 2021 18:39:01 |

US3372284

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

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 19:01:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 18:39:04 |

US3372284

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

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'I' | System | 28 Jan 2021 18:39:04 |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 16 Mar 2021 13:58:03 |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '4 Feb 2021' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 16 Mar 2021 13:58:03 |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 16 Mar 2021 13:58:03 |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) | 16 Mar 2021 13:58:03 |
| | (b) (4) | |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:13:06 |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'I' | System | 26 Feb 2021 16:13:06 |

US3372284

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '1' | System | 26 Feb 2021 16:13:06 |
| DataPoint set to visible. | System | 26 Feb 2021 16:13:06 |

US3372284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:13:31 |

US3372284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:13:31 |

US3372284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:13:31 |

US3372284

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'OLD29' | System | 26 Feb 2021 16:13:31 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '08:46' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '25 Feb 2021 08:46' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '36.5' C | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Other (Other)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'FOREHEAD' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'bpm' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '17' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'breaths/min' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '138' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '92' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '10:18' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '25 Feb 2021 10:18' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '36.5' C | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Other (Other)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'FOREHEAD' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '79' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'bpm' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '17' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'breaths/min' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '141' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '85' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 26 Feb 2021 16:16:47 |

US3372284

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:53 |

US3372284

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:16:53 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

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) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mRNA-1273' | System | 26 Feb 2021 16:17:06 |
| DataPoint set to visible. | System | 26 Feb 2021 16:13:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '09:45' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '25 Feb 2021 09:45' | System | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). | (b) (4) | 26 Feb 2021 16:17:12 |
| Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System). | System | 26 Feb 2021 16:17:12 |
| User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Feb 2021 16:17:12 |
| User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). | System | 26 Feb 2021 16:17:06 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'ONCE' | System | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:16:42

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'INTRAMUSCULAR' | System | 26 Feb 2021 16:17:06 |

US3372284

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 16:17:16 |

US3372284

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'I' | System | 26 Feb 2021 16:17:16 |

US3372284

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) | 04 Mar 2021 19:26:17 |

US3372284

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered '4 Mar 2021' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 04 Mar 2021 19:26:17 |

US3372284

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Danielle Theodore (b) (4) | 04 Mar 2021 19:26:17 |

US3372284

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:16:42

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered empty. | (b) (4) Danielle Theodore (b) (4) | 04 Mar 2021 19:26:17 |
| | (b) (4) | |

US3372284

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Yes (Y)' | (b) (4) Danielle Theodore (b) (4) (b) (4) | 04 Mar 2021 19:26:27 |

US3372284

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:16:42

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'I' | System | 04 Mar 2021 19:26:27 |

US3372284

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:26 |

US3372284

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:26 |

US3372284

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:26 |

US3372284

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:16:42

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'OLD57' | System | 26 Mar 2021 21:32:26 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '11:45' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '26 Mar 2021 11:45' | System | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '36.5' C | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Other (Other)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'forehead' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '84' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'bpm' | System | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '17' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'breaths/min' | System | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '123' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered 'mmHg' | System | 26 Mar 2021 21:32:52 |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| | | |

US3372284

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:16:42

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| | | |

US3372284

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:57 |

US3372284

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:16:42

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:32:57 |

US3372284

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:33:07 |

US3372284

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:33:07 |

US3372284

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 13:33:37 |
| User entered '11:58' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 21:33:07 |

US3372284

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:16:42

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 00:41:55 |
| User entered '26 Mar 2021 11:58' | System | 26 Mar 2021 21:33:07 |

US3372284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:16:42

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 13:49:39 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 16:48:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:48 |
| User closed query 'Per CDM-Did the participant experience any adverse events? is recorded as 'No',however,adverse events have been reported in the adverse events form.Kindly consider to verify and update data appropriately.Thank you.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 16:32:12 |
| Query 'Per CDM-Did the participant experience any adverse events? is recorded as 'No',however,adverse events have been reported in the adverse events form.Kindly consider to verify and update data appropriately.Thank you.' answered with 'data updated' (Site from DM). | Mary Sergalis (b) (4) | 09 Dec 2020 21:28:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Mary Sergalis (b) (4) | 09 Dec 2020 21:28:17 |
| User opened query 'Per CDM-Did the participant experience any adverse events? is recorded as 'No',however,adverse events have been reported in the adverse events form.Kindly consider to verify and update data appropriately.Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 04:51:47 |
| User entered 'No (N)' reason for change: Data Entry Error | Mary Sergalis (b) (4) | 22 Oct 2020 13:24:40 |
| User entered 'Yes (Y)' | Mary Sergalis (b) (4) | 29 Sep 2020 00:13:24 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| | | |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #4 and 5 (SORE THROAT and PYREXIA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Feb 2021 09:02:08 |
| User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). | (b) (4), (b) (6) | 04 Feb 2021 08:59:58 |
| Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'data correct as is' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 03 Feb 2021 21:59:17 |
| Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #4 and 5 (SORE THROAT and PYREXIA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' answered with 'unrelated AEs' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 03 Feb 2021 21:59:02 |
| User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #4 and 5 (SORE THROAT and PYREXIA), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 06:48:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:22:43 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).</td <td>(b) (4), (b) (6)</td> <td>14 Dec 2020 17:22:31</td> | (b) (4), (b) (6) | 14 Dec 2020 17:22:31 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Nov 2020 15:40:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 19 Nov 2020 15:40:04 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Nov 2020 15:25:00 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 19 Nov 2020 15:25:00 |
| Data point term sent to Coder | System | 19 Nov 2020 15:24:29 |
| User entered 'MILD COUGH' | Jennifer Torres (b) (4) | 19 Nov 2020 15:23:33 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:46 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:47 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:48 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:50 |
| User entered '14 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:52 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User entered empty. | System | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 01:05:36 |
| User closed query 'Please update this adverse event. According to MR end date is 18Dec2021. Please review and clarify or reconcile. Thanks,(b) (6) (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 01:05:33 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 18:37:11 |
| Query 'Please update this adverse event. According to MR end date is 18Dec2021. Please review and clarify or reconcile. Thanks,(b) (6) answered with 'Data updated.' (Site from CRA). | (b) (4), (b) (6) | 29 Mar 2021 18:08:58 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| Signature has been broken. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| User opened query 'Please update this adverse event. According to MR end date is 18Dec2021. Please review and clarify or reconcile. Thanks,(b) (6) (Site from CRA). | (b) (4), (b) (6) | 18 Mar 2021 15:39:59 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:22:54 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 01:05:38 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 18:37:11 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| Signature has been broken. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| User entered '18 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:43:07 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered empty. | Jennifer Torres (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:56 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User entered empty. | System | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:22:58 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:00 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:03 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:04 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:06 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:08 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:09 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:13 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:12 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

US3372284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:17 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:15 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:18 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:19 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:23:23 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 21:13:00 |
| User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 21:12:58 |
| Query 'Please verify if this should be none as per CRF guidelines.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 15 Feb 2021 22:25:15 |
| User entered 'None (NONE)' reason for change: Data Entry Error | Peter Jacob (b) (4) (b) (4) | 15 Feb 2021 22:23:12 |
| User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 18:33:21 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

None

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 22 Apr 2021 16:39:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 13:37:35 |
| Signature has been broken. | (b) (4), (b) (6) | 21 Apr 2021 16:31:40 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 16:31:40 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 18:37:11 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| Signature has been broken. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:43:12 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 17 Feb 2021 21:13:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 21:13:01 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 16 Feb 2021 07:25:36 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) | 15 Feb 2021 22:25:14 |
| DataPoint Un-verified. | Peter Jacob (b) (4) | 15 Feb 2021 22:23:12 |
| User entered '0' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:23:12 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

None

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 11 Jan 2021 06:48:46 |
| | | |
| | (b) (4), (b) (6) | 22 Dec 2020 18:23:44 |
| | | |
| User entered 'I' | Jennifer Torres (b) (4) | 19 Nov 2020 15:23:33 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 22 Apr 2021 16:39:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 13:37:37 |
| User closed query 'According to MR no medication was given. Please review and clarify or reconcile. Thanks, (b) (6) (Site from CRA). | (b) (4), (b) (6) | 22 Apr 2021 13:37:22 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 05:09:02 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'data updated' (Site from DM). | (b) (4), (b) (6) | 21 Apr 2021 16:31:50 |
| Signature has been broken. | (b) (4), (b) (6) | 21 Apr 2021 16:31:40 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 16:31:40 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. (Site from DM). | (b) (4), (b) (6) | 05 Apr 2021 05:46:58 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 18:37:11 |
| Query 'According to MR no medication was given. Please review and clarify or reconcile. Thanks, (b) (6) answered with 'Data updated.' (Site from CRA). | (b) (4), (b) (6) | 29 Mar 2021 18:09:16 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| Signature has been broken. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:43:14 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User opened query 'According to MR no medication was given. Please review and clarify or reconcile. Thanks, (b) (6) (Site from CRA). User signature succeeded. | (b) (4), (b) (6) | 18 Mar 2021 15:42:51 |
| | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Un-verified. | (b) (4) | |
| | Peter Jacob (b) (4) | 15 Feb 2021 22:23:12 |
| | (b) (4) | |
| User entered '1' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:23:12 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:09 |
| | | |
| User entered '0' | Jennifer Torres (b) (4) | 19 Nov 2020 15:23:33 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:24:11 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 01:06:54 |
| User closed query 'Please update. Thanks, (b) (6) (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 01:06:52 |
| User signature succeeded. | Mira Baron (b) (4) | 29 Mar 2021 18:37:11 |
| Query 'Please update. Thanks, (b) (6) answered with 'Data updated.' (Site from CRA). | (b) (4), (b) (6) | 29 Mar 2021 18:09:33 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| Signature has been broken. | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4), (b) (6) | 29 Mar 2021 18:08:34 |
| Data Entry Error | | |
| DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 15:43:51 |
| User opened query 'Please update. Thanks, (b) (6) (Site from CRA). | (b) (4), (b) (6) | 18 Mar 2021 15:43:49 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4) | |
| | Jennifer Torres (b) (4) | 19 Nov 2020 15:23:33 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:33:28 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:13 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:24:18 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User entered '0' | System | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| User entered '0' | System | 19 Nov 2020 15:23:33 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:16:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:59:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Feb 2021 09:00:26 |
| Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'data updated' (Site from DM). | Peter Jacob (b) (4) (b) (4) | 03 Feb 2021 22:01:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:36 |
| User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 17:22:55 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Nov 2020 15:25:00 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Nov 2020 15:25:00 |
| Data point term sent to Coder | System | 19 Nov 2020 15:24:29 |
| User entered 'SORE THROAT' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:24:39 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:37 |
| User entered 'No (N)' | Jennifer Torres (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:24:54 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 20:02:50 |
| User closed query 'Please verify, noted as 15Nov2020 in source.' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 20:02:47 |
| Query 'Please verify, noted as 15Nov2020 in source.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 03 Feb 2021 22:02:13 |
| User entered '15 Nov 2020' reason for change: Data Entry Error | Peter Jacob (b) (4) (b) (4) | 03 Feb 2021 22:02:09 |
| User opened query 'Please verify, noted as 15Nov2020 in source.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 18:25:25 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:24:56 |
| User entered '14 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:25:28 |
| User entered empty. | Jennifer Torres (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User entered empty. | System | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:30 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:32 |
| User entered '17 Nov 2020' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:25:35 |
| User entered empty. | Jennifer Torres (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User entered empty. | System | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:37 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:38 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:40 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:41 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:45 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:25:48 |
| User entered empty. | Jennifer Torres (b) (4) | 19 Nov 2020 15:24:14 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:25:49 |
| User entered empty. | Jennifer Torres (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:25:52 |
| User entered empty. | Jennifer Torres (b) (4) | 19 Nov 2020 15:24:14 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:54 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:26:01 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:26:00 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:58 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:25:57 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:26:12 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 18:58:22 |
| User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 26 Feb 2021 18:58:19 |
| Query 'Please verify if this should be none as per CRF guidelines.' answered with 'data correct as is' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 15 Feb 2021 22:33:16 |
| User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 20:03:37 |
| User closed query 'Please verify if this should be no related as in CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 10 Feb 2021 20:02:58 |
| Query 'Please verify if this should be no related as in CRF guidelines.' answered with 'please clarify' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 03 Feb 2021 22:02:19 |
| User opened query 'Please verify if this should be no related as in CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 18:30:16 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Dec 2020 18:29:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:26:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

None

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:29:25 |
| User entered 'I' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:29:26 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:29:23 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:29:27 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:29:30 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:29:33 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User entered '0' | System | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |
| User entered '0' | System | 19 Nov 2020 15:24:14 |

US3372284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:16:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:44 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 13:58:34 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:41:22 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|--------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Feb 2021 20:32:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:43:42 |
| User entered | System | 14 Dec 2020 18:09:46 |
| 'USA-US056-2020-mRNA-1273-P301000009' | | |
| User entered 'New' | (b) (4), (b) (6) | 14 Dec 2020 18:09:46 |
| | | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:43:46 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 12 Dec 2020 00:11:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 12 Dec 2020 00:11:51 |
| Data point term sent to Coder | System | 12 Dec 2020 00:10:41 |
| User entered 'COVID-19' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User closed query 'Please verify, noted as having a home visit on 03Dec2020.' (Site from CRA). | (b) (4) | 17 Feb 2021 16:21:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:20:58 |
| Query 'Please verify, noted as having a home visit on 03Dec2020.' answered with 'data updated' (Site from CRA). | (b) (4), (b) (6) | 15 Feb 2021 22:45:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| User opened query 'Please verify, noted as having a home visit on 03Dec2020.' (Site from CRA). | (b) (4) | 22 Dec 2020 18:44:55 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Dec 2020 00:10:10 |
| | Jennifer Torres (b) (4) | |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:45:52 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:45:51 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 16:21:09 |
| User closed query 'PV Query: COVID-19 symptoms have been reported starting on 30 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 20:33:41 |
| Query 'PV Query: COVID-19 symptoms have been reported starting on 30 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'data updated' (Site from Safety). | Peter Jacob (b) (4) | 15 Feb 2021 22:45:55 |
| | (b) (4) | |
| DataPoint Un-verified. | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| | (b) (4) | |
| User entered '30 Nov 2020' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| | (b) (4) | |
| User opened query 'PV Query: COVID-19 symptoms have been reported starting on 30 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety). | (b) (4), (b) (6) | 30 Dec 2020 21:18:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:45:57 |
| User entered '03 Dec 2020' | Jennifer Torres (b) (4) | 12 Dec 2020 00:10:10 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:02 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 16:21:20 |
| User closed query 'Please verify, AE stop date should be last day of symptoms.' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 16:21:18 |
| Query 'Please verify, AE stop date should be last day of symptoms.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) | 15 Feb 2021 22:45:57 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| | (b) (4) | |
| User opened query 'Please verify, AE stop date should be last day of symptoms.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 16:55:48 |
| User entered 'Yes (Y)' | Jennifer Torres (b) (4) | 12 Dec 2020 00:10:10 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 16:21:55 |
| User closed query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 20:33:01 |
| Query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' answered with 'data updated' (Site from Safety). | Peter Jacob (b) (4) | 15 Feb 2021 22:45:59 |
| User entered '18 Dec 2020' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4) | 15 Feb 2021 22:41:08 |
| User opened query 'PV Query: Please provide the event end date (when symptoms resolved), when available.' (Site from Safety). | (b) (4), (b) (6) | 18 Dec 2020 14:14:02 |
| User entered empty. | Jennifer Torres (b) (4) | 12 Dec 2020 00:10:10 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 16:21:57 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:19 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| User closed query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Mar 2021 15:03:21 |
| Query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given. ' answered with 'No treatment given. Subject did not require' (Site from DM). | Mary Sergalis (b) (4) | 10 Mar 2021 17:03:04 |
| User opened query 'Per DM CLR: Serious= YES. However, no Con Med or therapeutic Con Procedure recorded for this condition which is unexpected. Review and update CM/Con proc if given or provide comment if no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 07:48:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:22:39 |
| DataPoint Un-verified. | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:46:21 |
| User entered 'No (N)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:18 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:16 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:25 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:26 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:27 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:28 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:30 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:35 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:46:33 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 16:22:12 |
| User entered '1' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| User entered '0' | (b) (4) Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:49:00 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:48:56 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 16:22:19 |
| User closed query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 16:22:16 |
| Query 'Please verify if this should be none as per CRF guidelines.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) | 15 Feb 2021 22:46:02 |
| | (b) (4) | |
| User opened query 'Please verify if this should be none as per CRF guidelines.' (Site from CRA). | (b) (4), (b) (6) | 22 Dec 2020 18:48:57 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jennifer Torres (b) (4) | 12 Dec 2020 00:10:10 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

None

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 16:22:22 |
| User entered 'I' | Jennifer Torres (b) (4) | 12 Dec 2020 00:10:10 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 16:22:20 |
| 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 Feb 2021 20:33:46 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'data updated' (Site from Safety). | Peter Jacob (b) (4) (b) (4) | 15 Feb 2021 22:46:04 |
| 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) | 18 Dec 2020 14:14:27 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:48:20 |
| User entered '0' | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 16:22:28 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 20:33:49 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated' (Site from Safety). | Peter Jacob (b) (4) | 15 Feb 2021 22:46:07 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| Data Entry Error | (b) (4) | |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 18 Dec 2020 14:13:44 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Jennifer Torres (b) (4) | 12 Dec 2020 00:10:10 |
| | (b) (4) | |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 16:22:30 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[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) | 30 Mar 2021 13:42:32 |
| 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 'Data updated. ConMeds for this AE have been recorded in the ConMeds eCRF.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:12:39 |
| 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) | 19 Mar 2021 20:55:02 |
| User signature succeeded. | Mira Baron (b) (4) | 16 Mar 2021 19:26:26 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 16:22:34 |
| User entered 'subject tested positive for COVID-19' reason for change: Data Entry Error | Peter Jacob (b) (4) | 15 Feb 2021 22:41:08 |
| User entered empty. | Jennifer Torres (b) (4) (b) (4) | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Feb 2021 22:41:08 |
| User entered '0' | System | 12 Dec 2020 00:10:10 |

US3372284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:16:42

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Feb 2021 22:41:08 |
| User entered '0' | System | 12 Dec 2020 00:10:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:16:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 13:49:39 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:48:45 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 18:11:13 |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:54:42 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User closed query 'Please verify if tylenol and tussin CF should be entered as per source.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 19:25:41 |
| Query 'Please verify if tylenol and tussin CF should be entered as per source.' answered with 'data updated' (Site from CRA). | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:28:31 |
| User opened query 'Please verify if tylenol and tussin CF should be entered as per source.' (Site from CRA). | (b) (4), (b) (6) | 23 Dec 2020 15:34:19 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Oct 2020 22:58:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Oct 2020 22:58:23 |
| Data point term sent to Coder | System | 11 Oct 2020 22:57:08 |
| User entered 'acetaminophen' | Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered 'No (N)' | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Indication](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'generalized osteoarthritis' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered '500' | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered 'mg (mg)' | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'once daily (QD)' | (b) (4) Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Oral (ORAL)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered 'un UNK 2008' | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Peter Jacob (b) (4) | 11 Oct 2020 22:56:38 |
| | (b) (4) | |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Oct 2020 22:56:38 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Oct 2020 22:59:23 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Oct 2020 22:59:23 |
| Data point term sent to Coder | System | 11 Oct 2020 22:58:09 |
| User entered 'influenza vaccine' | Peter Jacob (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Indication](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'influenza prophylaxis/prevention' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0.5' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'mL (mL)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'once (ONCE)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'un Dec 2019' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'un Dec 2019' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Peter Jacob (b) (4) (b) (4) | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User entered empty. | System | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User entered empty. | System | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:14 |
| User entered empty. | System | 11 Oct 2020 22:57:13 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Nov 2020 20:52:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Nov 2020 20:52:00 |
| Data point term sent to Coder | System | 23 Nov 2020 20:51:01 |
| User entered 'Influenza vaccine' | Elena Acosta (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Influenza prevention' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0.5' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'mL (mL)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'once (ONCE)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '8 Nov 2020' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '8 Nov 2020' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User entered empty. | System | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User entered empty. | System | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:19 |
| User entered empty. | System | 23 Nov 2020 20:51:00 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Nov 2020 21:40:10 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Nov 2020 21:40:10 |
| Data point term sent to Coder | System | 23 Nov 2020 21:39:40 |
| User entered 'Influenza vaccine' | Elena Acosta (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Influenza prevention' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0.5' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'mL (mL)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'once (ONCE)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered empty. | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '27 Oct 2020' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '0' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered '27 Oct 2020' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| User entered 'No (N)' | (b) (4) Elena Acosta (b) (4) (b) (4) | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User entered empty. | System | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User entered empty. | System | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:24 |
| User entered empty. | System | 23 Nov 2020 21:39:10 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:57 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 16:24:42 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 16:24:42 |
| Data point term sent to Coder | System | 23 Dec 2020 16:23:41 |
| User entered 'tylenol' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:58 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:59 |
| User entered 'pyrexia' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:02 |
| User entered '500' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:03 |
| User entered 'mg (mg)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:05 |
| User entered empty. | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:07 |
| User entered 'as needed (PRN)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:09 |
| User entered empty. | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:08 |
| User entered 'Oral (ORAL)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:11 |
| User entered empty. | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:12 |
| User entered '06 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:14 |
| User entered '0' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:15 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:16 |
| User entered '10 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:45:18 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User entered empty. | System | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User entered empty. | System | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 06:03:32 |
| User entered empty. | System | 23 Dec 2020 16:22:41 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLPRO PANOLAMINE HYDROCHLORIDE, PRODUCTSYNONYM: TUSSIN CF - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Apr 2021 18:22:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Apr 2021 18:22:09 |
| Data point term sent to Coder | System | 12 Apr 2021 17:10:14 |
| Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' canceled (Site from System). | Coder Import (b) (4) (b) (4) | 12 Apr 2021 17:09:28 |
| User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System). | Coder Import (b) (4) (b) (4) | 08 Apr 2021 13:41:39 |
| User signature succeeded. | Mira Baron (b) (4) (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Jan 2021 18:44:05 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLEPH RINE HYDROCHLORIDE, PRODUCTSYNONYM: Q-TUSSIN CF [DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLEPH RINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 21:13:17 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Tussin-CF' | Coder Import (b) (4) (b) (4) System Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 21:13:17 23 Dec 2020 16:27:43 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:07 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:08 |
| User entered 'cough' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:09 |
| User entered '10' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:11 |
| User entered 'mL (mL)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:12 |
| User entered empty. | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:14 |
| User entered 'as needed (PRN)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:17 |
| User entered empty. | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:16 |
| User entered 'Oral (ORAL)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:19 |
| User entered empty. | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:20 |
| User entered '10 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:22 |
| User entered '0' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:23 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:24 |
| User entered '17 Dec 2020' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User signature succeeded. | Mira Baron (b) (4) | 22 Apr 2021 16:39:22 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 16:31:21 |
| Signature has been broken. | (b) (4), (b) (6) | 21 Apr 2021 16:31:21 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Apr 2021 16:31:21 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Jan 2021 18:44:26 |
| User entered 'No (N)' | Peter Jacob (b) (4) (b) (4) | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User entered empty. | System | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User entered empty. | System | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:16:42

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:08 |
| User entered empty. | System | 23 Dec 2020 16:27:26 |

US3372284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:16:42

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 16 Feb 2021 18:19:05 |
| | (b) (4) | |
| User entered 'No (N)' | Peter Jacob (b) (4) | 11 Oct 2020 22:54:32 |
| | (b) (4) | |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'USA-US056-2020-MRNA-1273-P301000009' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:09 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:13 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Mira' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Baron' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '2277 Palm beach Lakes Blvd' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: City](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'West Palm Beach' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '33409' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'US' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User entered '4' | System | 30 Mar 2021 13:43:58 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| | (b) (4) | |
| User entered '3' | System | 16 Feb 2021 20:35:03 |
| User entered '2' | System | 23 Dec 2020 18:00:55 |
| User entered '1' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'USA-US056-2020-MRNA-1273-P301000009' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:09 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:13 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Mira' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Baron' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '2277 Palm beach Lakes Blvd' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: City](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'West Palm Beach' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '33409' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'US' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User entered '4' | System | 30 Mar 2021 13:43:58 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| | (b) (4) | |
| User entered '3' | System | 16 Feb 2021 20:35:03 |
| User entered '2' | System | 23 Dec 2020 18:00:55 |
| User entered '1' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:42

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| User entered '14/Dec/2020 13:10' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:16:42

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. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'I' | (b) (4), (b) (6) | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'USA-US056-2020-MRNA-1273-P301000009' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:09 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:13 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Mira' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Baron' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '2277 Palm beach Lakes Blvd' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: City](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'West Palm Beach' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '33409' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'US' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User entered '4' | System | 30 Mar 2021 13:43:58 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| | (b) (4) | |
| User entered '3' | System | 16 Feb 2021 20:35:03 |
| User entered '2' | System | 23 Dec 2020 18:00:55 |
| User entered '1' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:42

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:28 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered '23/Dec/2020 13:00' | (b) (4) System | 23 Dec 2020 18:00:55 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:16:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:27 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 23 Dec 2020 18:01:01 |
| User entered 'I' | (b) (4), (b) (6) | 23 Dec 2020 18:00:55 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'USA-US056-2020-MRNA-1273-P301000009' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:09 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:13 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Mira' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Baron' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '2277 Palm beach Lakes Blvd' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: City](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'West Palm Beach' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '33409' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'US' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User entered '4' | System | 30 Mar 2021 13:43:58 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| | (b) (4) | |
| User entered '3' | System | 16 Feb 2021 20:35:03 |
| User entered '2' | System | 23 Dec 2020 18:00:55 |
| User entered '1' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:16:42

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:20:37 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered '16/Feb/2021 20:35' | (b) (4) System | 16 Feb 2021 20:35:03 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:16:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:20:36 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:35:03 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'USA-US056-2020-MRNA-1273-P301000009' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:09 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 16:19:13 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 16 Feb 2021 20:34:52 |
| Un-reviewed for Safety. | System | 15 Feb 2021 22:41:08 |
| DataPoint Un-verified. | System | 15 Feb 2021 22:41:08 |
| User entered 'Yes (Y)' | System | 15 Feb 2021 22:41:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'No (N)' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Mira' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'Baron' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '2277 Palm beach Lakes Blvd' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: City](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'West Palm Beach' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered '33409' | System | 14 Dec 2020 18:09:46 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 18:18:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Dec 2020 18:10:33 |
| User entered 'US' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:16:42

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User entered '4' | System | 30 Mar 2021 13:43:58 |
| User signature succeeded. | Mira Baron (b) (4) | 17 Feb 2021 02:51:31 |
| | (b) (4) | |
| User entered '3' | System | 16 Feb 2021 20:35:03 |
| User entered '2' | System | 23 Dec 2020 18:00:55 |
| User entered '1' | System | 14 Dec 2020 18:10:28 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:16:42

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 02:17:28 |
| User signature succeeded. | Mira Baron (b) (4) | 30 Mar 2021 14:28:52 |
| User entered '30/Mar/2021 09:43' | (b) (4) System | 30 Mar 2021 13:43:58 |

US3372284

Folder: SAE USA-US056-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

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Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 02:17:30 |
| User signature succeeded. | Mira Baron (b) (4) | 30 Mar 2021 14:28:52 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 13:43:58 |