

US3142255 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:04:27

All time stamps listed in this document are displayed in GMT

US3142255

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

[Participant ID](#)

US3142255

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

US3142255

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy) | (b) (6)1996 |
| Age | 23 |
| Age Units | YEARS |
| Age (Derived) | 23 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 21:19:34

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| | |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 26 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) 18 Apr 2021 21:19:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 21:19:34

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 21:19:34

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | HEPATITIS C |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN FEB 2020 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | FEB 2020 |
| Stop Year (derived) | 2020 |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 21:19:34

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 26 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:25 (24 HR) |
| Vital Signs Date and Time (derived) | 26 AUG 2020 10:25 |
| Height (<i>xxx.x</i>) | 71 in |
| Weight (<i>xxx.x</i>) | 154.0 lb |
| BMI (<i>xxx.x</i>) | 21.52355 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) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:19:34

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

WORKS IN STUDENT SERVICES

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) 18 Apr 2021 21:19:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 26 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) 18 Apr 2021 21:19:34

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What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108719

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) 18 Apr 2021 21:19:34

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| | |
|--------|---------------|
| 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) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 26 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:25 (24 HR) |
| Vital Signs Date and Time (derived) | 26 AUG 2020 10:25 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 26 AUG 2020 |
| Time of assessment (00:00-23:59) | 11:30 (24 HR) |
| Vital Signs Date and Time (derived) | 26 AUG 2020 11:30 |
| Temperature (xxx.x) | 98.4 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 54 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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) 18 Apr 2021 21:19:34

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Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

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

Treatment Date and Time (derived) 26 AUG 2020 11:00

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) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

10:39 (24 HR)

Collection date and time (derived)

26 AUG 2020 10:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| Collection date (dd MMM yyyy) | | | 26 AUG 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:39 | 26 AUG 2020 10:39 |
| Nasopharyngeal Swab 2 | Yes | 10:39 | 26 AUG 2020 10:39 |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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: 11 Aug 2021 22:04:27

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 AUG 2020 11:20

PC Close Date & Time

26 AUG 2020 13:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 AUG 2020 14:45

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 11:20

PC Close Date & Time

26 AUG 2020 13:50

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 14:45

PC Close Date & Time

27 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

02 SEP 2020 06:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 AUG 2020 11:20

PC Close Date & Time

26 AUG 2020 13:50

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 AUG 2020 14:45

PC Close Date & Time

27 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

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)

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US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

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)

50 of 2554

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

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 ☐

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EAB) (1725)

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US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

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 ☒

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 06:08 |
| PC Open Date & Time | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:04:27

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:04:27

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:31

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 23 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 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|-------------------------------------------|
| 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) | 23 SEP 2020 |
| Time of assessment (00:00-23:59) | 08:36 (24 HR) |
| Vital Signs Date and Time (derived) | 23 SEP 2020 08:36 |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 82 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 127 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|--------------------------------------------|
| 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) | 23 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:50 (24 HR) |
| Vital Signs Date and Time (derived) | 23 SEP 2020 09:50 |
| Temperature (xxx.x) | 98.9 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 09:19 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 09:19

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

US3142255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

23 SEP 2020 08:55

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| Collection date (dd MMM yyyy) | | | 23 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 08:50 | 23 SEP 2020 08:50 |
| Nasopharyngeal Swab 2 | Yes | 08:50 | 23 SEP 2020 08:50 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

98.9 °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

23 SEP 2020 09:50

PC Open Date & Time

23 SEP 2020 09:39

PC Close Date & Time

23 SEP 2020 12:09

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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 97.7 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 23 SEP 2020 17:24

PC Open Date & Time 23 SEP 2020 13:04

PC Close Date & Time 24 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

25 SEP 2020 14:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 21:28

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 06:18

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

23 SEP 2020 09:50

PC Open Date & Time

23 SEP 2020 09:39

PC Close Date & Time

23 SEP 2020 12:09

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

23 SEP 2020 17:20

PC Open Date & Time

23 SEP 2020 13:04

PC Close Date & Time

24 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

25 SEP 2020 14:17

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

26 SEP 2020 21:28

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

28 SEP 2020 06:18

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 6 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Please record - PAIN AT INJECTION SITE. Please select one response below | None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/> |
| Is there any REDNESS AT INJECTION SITE? | Yes <input type="radio"/> No <input type="radio"/> |
| Please record - REDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site redness with the ruler provided. | |
| Is there any SWELLING/HARDNESS AT INJECTION SITE? | Yes <input type="radio"/> No <input type="radio"/> |
| Please record - SWELLING/HARDNESS AT INJECTION SITE (in mm) Measure the largest size across any injection site swelling/hardness with the ruler provided. | |
| Please record - UNDERARM GLAND SWELLING OR TENDERNESS. Please select one response below | None <input type="radio"/> Does not interfere with activity <input type="radio"/> Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity <input type="radio"/> Any use of prescription pain reliever or prevents daily activity <input type="radio"/> |
| PC Time Stamp | |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 23 SEP 2020 09:50 |
| PC Open Date & Time | 23 SEP 2020 09:39 |
| PC Close Date & Time | 23 SEP 2020 12:09 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 23 SEP 2020 17:20 |
| PC Open Date & Time | 23 SEP 2020 13:04 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

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 ☒

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 14:17 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

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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US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 SEP 2020 21:29 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

102 of 2554

EAB) (1725)

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 06:18 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3142255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 21 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 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|----------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 21 OCT 2020 |
| Time of assessment (00:00-23:59) | 09:17 (24 HR) |
| Vital Signs Date and Time (derived) | 21 OCT 2020 09:17 |
| Temperature (xxx.x) | 98.2 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 55 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 125 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3142255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

09:27 (24 HR)

Collection date and time (derived)

21 OCT 2020 09:27

US3142255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 07:19:04

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 02 NOV 2020 09:43:16 |
| Patient Cloud Open Date & Time | 02 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 06 NOV 2020 23:59 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

09 NOV 2020 05:05:16

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <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 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"/> |
| Have 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 | 20 NOV 2020 02:28:46 |
| Patient Cloud Open Date & Time | 20 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 24 NOV 2020 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 96 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 NOV 2020 06:21:17 |
| Patient Cloud Open Date & Time | 27 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 01 DEC 2020 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 07:03:49

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 04:28:12

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

18 DEC 2020 08:21:24

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 | 25 DEC 2020 16:00:46 |
| Patient Cloud Open Date & Time | 25 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 29 DEC 2020 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

01 JAN 2021 00:14:40

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

08 JAN 2021 18:15:20

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 145 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 15 JAN 2021 06:55:48 |
| Patient Cloud Open Date & Time | 15 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 19 JAN 2021 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

22 JAN 2021 10:21:58

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 FEB 2021 07:25:15 |
| Patient Cloud Open Date & Time | 05 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 09 FEB 2021 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

12 FEB 2021 00:01:15

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 180 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <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 | 26 FEB 2021 15:27:14 |
| Patient Cloud Open Date & Time | 26 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 02 MAR 2021 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 194 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 05 MAR 2021 06:53:57 |
| Patient Cloud Open Date & Time | 05 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 09 MAR 2021 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 201 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 12 MAR 2021 07:26:05 |
| Patient Cloud Open Date & Time | 12 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 16 MAR 2021 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

19 MAR 2021 06:28:19

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

26 MAR 2021 07:16:33

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

02 APR 2021 07:11:25

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

09 APR 2021 00:02:23

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

16 APR 2021 00:09:10

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

23 APR 2021 03:48:07

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

30 APR 2021 00:02:19

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 383 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 01 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 05 OCT 2021 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

14 JAN 2022 00:01

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18 JAN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

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25 JAN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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08 FEB 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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22 FEB 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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 <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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 MAR 2022 00:01 |
| Patient Cloud Close Date & Time | 29 MAR 2022 23:59 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 586 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 754 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 775 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| TIMEPOINT | DAY 789 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

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

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

| 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"/> |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3142255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:04:27

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| No | | 05 MAR 2021 06:54:07 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:31

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:31

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:39:31

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:39:31

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 07 APR 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 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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) _____

US3142255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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.

US3142255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 APR 2021

Collection time (00:00-23:59)

16:46 (24 HR)

Collection date and time (derived)

07 APR 2021 16:46

US3142255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

Date of Contact 16 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☒

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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"/> |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|---------------|----------------------------------|
| | 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 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 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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US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | 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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EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|---------------|----------------------------------|
| | 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 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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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | 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 16 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|-------------------------|----------|----------------------------------|
| 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 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 (3)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | 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 16 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

Symptom Day

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.2 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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Form: Symptom Log (4)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" 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 type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 (4)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|-------------------------|----------|----------------------------------|
| 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 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 (5)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 97 % | |
| 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 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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Form: Symptom Log (5)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 (5)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:32:43

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| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 95 % | |
| O2 Saturation Units | % | |
| Temperature | 99.4 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:32:43

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (7)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 99.6 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 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input checked="" type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input checked="" 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) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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"/> |

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Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 97 % | |
| 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 21 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| O2 Saturation Units | % | |
| Temperature | 99.2 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

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Form: Symptom Log (9)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|-------------------------|----------|----------------------------------|
| 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 checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 22 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 96 % | |
| 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 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (10)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" 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 type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 (10)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 23 NOV 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 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (11)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 (11)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 24 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| 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 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 16 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 25 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| 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 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Form: Symptom Log (13)

Data signed: (b) (4) 18 Apr 2021 21:32:43

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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" 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 (13)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (14)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|----------------------|--------------------------|
| | 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 | 26 NOV 2020 | |
| Assessment Not Done | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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

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

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Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (15)

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Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|----------------------|--------------------------|
| | 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 | 27 NOV 2020 | |
| Assessment Not Done | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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

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EAB) (1725)

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Form: Symptom Log (15)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

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Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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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Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 28 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.4 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 type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Form: Symptom Log (16)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

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Data signed: (b) (4) 18 Apr 2021 21:32:43

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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 ☐

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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"/> |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|----------------------|--------------------------|
| | 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 | 29 NOV 2020 | |
| Assessment Not Done | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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"/> |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|----------------------|--------------------------|
| | 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 | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 98.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | 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 16 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input checked="" 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"/> |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|----------------------|-------------|----------------------------------|
| | 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 | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.4 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"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | | |
|------------------------|----------|----------------------------------|
| | 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 (20)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 16 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit | 16 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 checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 16 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) | 1 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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 _____

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

16 NOV 2020

End Date

16 NOV 2020

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☒

Start Date

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 16 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 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|----------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 16 NOV 2020 |
| Time of assessment (00:00-23:59) | 09:19 (24 HR) |
| Vital Signs Date and Time (derived) | 16 NOV 2020 09:19 |
| Height (xxx.x) | 71 in |
| Weight (xxx.x) | ND - Not Done |
| Temperature (xxx.x) | 98.2 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 107 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 59 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3142255

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 NOV 2020

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 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 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|----------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 17 DEC 2020 |
| Time of assessment (00:00-23:59) | 09:00 (24 HR) |
| Vital Signs Date and Time (derived) | 17 DEC 2020 09:00 |
| Height (xxx.x) | ND - Not Done |
| Weight (xxx.x) | ND - Not Done |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 43 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 132 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 DEC 2020

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

US3142255

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 DEC 2020

US3142255

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

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

| | |
|--------------------------|------------|
| Visit date (dd MMM yyyy) | 1 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 | UNBLND_DECIDE |
|------------|---------------|

US3142255

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

Form: Unblinding

Data signed: (b) (4) 03 May 2021 15:03:43

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 1 MAR 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>) | 24 FEB 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 |

US3142255

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

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

US3142255

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 01 MAR 2021 |
| Time of assessment (00:00-23:59) | 14:53 (24 HR) |
| Vital Signs Date and Time (derived) | 01 MAR 2021 14:53 |
| Temperature (xxx.x) | 98.6 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 105 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3142255

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 01 MAR 2021 |
| Time of assessment (00:00-23:59) | 15:44 (24 HR) |
| Vital Signs Date and Time (derived) | 01 MAR 2021 15:44 |
| Temperature (xxx.x) | 98.9 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3142255

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

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3142255

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

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

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) 01 MAR 2021

What was the treatment time? (00:00-23:59) 15:14 (24 HR)

Treatment Date and Time (derived) 01 MAR 2021 15:14

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

US3142255

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|-------------------------------|------------|
| Collection date (dd MMM yyyy) | 1 MAR 2021 |
|-------------------------------|------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 14:53 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|------------------|
| Collection date and time (derived) | 1 MAR 2021 14:53 |
|------------------------------------|------------------|

US3142255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 1 MAR 2021 |
| Collection time (00:00 - 23:59) | 15:04 |
| Collection Date and Time (derived) | 1 MAR 2021 15:04 |

US3142255

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

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:19:34

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 07 APR 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 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------------|-------------------------------------------|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | |
| Time of assessment (<i>00:00-23:59</i>) | |
| Vital Signs Date and Time (derived) | |
| Temperature (<i>xxx.x</i>) | |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | |
| Pulse units | |
| Respiratory Rate (<i>xxx</i>) | |
| Respiratory Rate units | |
| Systolic Blood Pressure (<i>xxx</i>) | |
| Systolic Blood Pressure units | |
| Diastolic Blood Pressure (<i>xxx</i>) | |
| Diastolic Blood Pressure units | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

| | |
|-------------------------------------|--------------------------------------------|
| 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) | 07 APR 2021 |
| Time of assessment (00:00-23:59) | 17:20 (24 HR) |
| Vital Signs Date and Time (derived) | 07 APR 2021 17:20 |
| 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 | TEMPORAL |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3142255

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 APR 2021

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

US3142255

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

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) 07 APR 2021

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 07 APR 2021 16:50

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

US3142255

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:32:44

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142255

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142255

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | USA-US064-2020-MRNA-1273-P30 1000005 |
| 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) | 13 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) | 17 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"/> |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

Yes ☒

No ☐

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

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication PAIN AFTER SECOND
VACCINATION (LOCATION AND
TYPE OF PAIN UNKNOWN)

Dose per administration 400

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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US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 21:32:43

Generated On: 11 Aug 2021 22:04:27

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3142255

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:04:27

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

US3142255

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:04:27

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 ☐

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US064-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RIPLEY |
| Investigator's Last Name | HOLLISTER |
| Site Address: Street | 4190 EAST WOODMEN ROAD SUITE 210 |
| Site Address: City | COLORADO SPRINGS |
| Site Address: State | |
| Site Address: Postal Code | 80920 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US064-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RIPLEY |
| Investigator's Last Name | HOLLISTER |
| Site Address: Street | 4190 EAST WOODMEN ROAD SUITE 210 |
| Site Address: City | COLORADO SPRINGS |
| Site Address: State | |
| Site Address: Postal Code | 80920 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 23/NOV/2020 14:58 |
| 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 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US064-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RIPLEY |
| Investigator's Last Name | HOLLISTER |
| Site Address: Street | 4190 EAST WOODMEN ROAD SUITE 210 |
| Site Address: City | COLORADO SPRINGS |
| Site Address: State | |
| Site Address: Postal Code | 80920 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 03/FEB/2021 17:25 |
| 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 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 02:45:32

Generated On: 11 Aug 2021 22:04:27

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US064-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | RIPLEY |
| Investigator's Last Name | HOLLISTER |
| Site Address: Street | 4190 EAST WOODMEN ROAD SUITE 210 |
| Site Address: City | COLORADO SPRINGS |
| Site Address: State | |
| Site Address: Postal Code | 80920 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 20/APR/2021 15:36 |
| 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

US3142255 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142255

Form: Participant Creation

Generated On: 11 Aug 2021 22:04:27

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'US3142255' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:09:56 |

US3142255

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 18:55:34 |

US3142255

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:09:57 |

US3142255

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Clinic (Clinic)' | Jami Wagner (b) (4) | 28 Aug 2020 18:55:34 |

US3142255

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'SCRN' | System | 28 Aug 2020 18:55:34 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '(b) (6)1996' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:09:58 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'YEARS' | System | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '23' | System | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

Sex

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Male (M)' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Ethnicity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

White

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'I' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

Unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:27

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:00 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Shelby Pickle (b) (4) | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Aug 2020' | System | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2020' | System | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Amendment 3 (3)' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Shelby Pickle (b) (4) | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:34:40 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:09:57 |

US3142255

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:27

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'I' | System | 26 Aug 2020 17:34:45 |

US3142255

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:34:45 |

US3142255

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:04:27

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 18:56:29 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

[Condition](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per DM CLR: Please specify the location of ASTIGMATISM (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Oct 2020 06:54:30 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Oct 2020 20:29:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Oct 2020 20:29:26 |
| Data point term sent to Coder | System | 19 Oct 2020 20:28:08 |
| Query 'Per DM CLR: Please specify the location of ASTIGMATISM (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'DONE' (Site from DM). | Jami Wagner (b) (4) (b) (4) | 19 Oct 2020 20:27:56 |
| Coding entries removed. | Jami Wagner (b) (4) (b) (4) | 19 Oct 2020 20:27:48 |
| User entered 'ASTIGMATISM, BILATERAL' reason for change: Data Entry Error | Jami Wagner (b) (4) (b) (4) | 19 Oct 2020 20:27:48 |
| User opened query 'Per DM CLR: Please specify the location of ASTIGMATISM (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 08 Sep 2020 21:41:03 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 18:58:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Aug 2020 18:58:38 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

[Condition](#)

| Audit | User | Time (GMT) |
|-------------------------------|---------------------|----------------------|
| Data point term sent to Coder | System | 28 Aug 2020 18:57:37 |
| User entered 'Astigmatism' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:35 |
| | (b) (4) | |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'UN UNK 2018' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Jan 2018' | System | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2018' | System | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:57:35 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

[Condition](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 18:59:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 18:59:40 |
| Data point term sent to Coder | System | 28 Aug 2020 18:58:37 |
| User entered 'Intermittent Back Pain' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'UN Jun 2019' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Jun 2019' | System | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2019' | System | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:57:55 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

[Condition](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 18:59:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 18:59:40 |
| Data point term sent to Coder | System | 28 Aug 2020 18:58:37 |
| User entered 'Hepatitis C' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:23 |
| | (b) (4) | |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'UN UNK 2018' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'UN Feb 2020' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Jan 2018' | System | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2018' | System | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Feb 2020' | System | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2020' | System | 28 Aug 2020 18:58:23 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Food intolerance syndromes, HLT: Sugar intolerance (excl glucose intolerance), PT: Lactose intolerance, LLT: Lactose intolerant - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 19:00:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 19:00:45 |
| Data point term sent to Coder | System | 28 Aug 2020 18:59:40 |
| User entered 'Lactose Intolerant' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'UN UNK 2018' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Jan 2018' | System | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2018' | System | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:58:42 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

[Condition](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 03:53:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Nov 2020 03:53:11 |
| Data point term sent to Coder | System | 28 Aug 2020 18:59:40 |
| User entered 'Matte Tea Sensitivity' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:59 |
| | (b) (4) | |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'UN UNK 2018' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

If No, please specify the stop date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'Jan 2018' | System | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '2018' | System | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 28 Aug 2020 18:58:59 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '10:25' | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '26 Aug 2020 10:25' | System | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '71' in | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |
| DataPoint set to visible. | System | 26 Aug 2020 17:34:45 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '154.0' lb | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |
| DataPoint set to visible. | System | 26 Aug 2020 17:34:45 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered '21.52355' | System | 28 Aug 2020 19:34:42 |
| DataPoint set to visible. | System | 26 Aug 2020 17:34:45 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'kg/m2' | System | 28 Aug 2020 19:34:42 |
| DataPoint set to visible. | System | 26 Aug 2020 17:34:45 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'bpm' | System | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'breaths/min' | System | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'mmHg' | System | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done. | Jami Wagner (b) (4) | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User entered 'mmHg' | System | 28 Aug 2020 19:34:42 |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| | | |

US3142255

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |

US3142255

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 19:34:57 |

US3142255

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Sep 2020 08:41:01 |
| User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System). | System | 28 Aug 2020 19:35:47 |
| User entered '28 Aug 2020' | Jami Wagner (b) (4) (b) (4) | 28 Aug 2020 19:34:57 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[Specify](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Works in Student Services' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | (b) (4) Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |
| | (b) (4) | |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

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 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'I' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '0' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:27

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 28 Aug 2020 19:35:36 |

US3142255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:47 |

US3142255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:47 |

US3142255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Clinic (Clinic)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:47 |

US3142255

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'VISIT1' | System | 28 Aug 2020 19:35:47 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:54:37 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '108719' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:54:37 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 26 Aug 2020 16:54:37 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

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) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:56 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

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) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:56 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:56 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:56 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' | Jami Wagner (b) (4) | 28 Aug 2020 19:35:56 |

US3142255

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:27

Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4) | |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'done' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 03:40:21 |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'done' (Site from DM). | Meghan York (b) (4) | 03 Nov 2020 21:46:16 |
| User entered 'No (N)' | (b) (4) | |
| User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | Meghan York (b) (4) | 03 Nov 2020 21:46:11 |
| Amendment Manager: DataPoint set to visible. | (b) (4) | |
| Amendment Manager inserted this DataPoint. | (b) (4), (b) (6) | 03 Nov 2020 13:10:00 |
| | System | 19 Sep 2020 08:03:19 |
| | System | 19 Sep 2020 08:03:18 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

Height

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM). | (b) (4) | 30 Sep 2020 17:32:05 |
| Query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' answered with 'done' (Site from DM). | Meghan York (b) (4) | 29 Sep 2020 15:25:55 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Sep 2020 15:25:51 |
| User opened query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM). | (b) (4), (b) (6) | 03 Sep 2020 15:13:52 |
| User entered '71' in | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

Weight

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Sep 2020 15:25:51 |
| User entered '154.0' lb | Meghan York (b) (4) | 28 Aug 2020 20:05:03 |
| | Jami Wagner (b) (4) | |
| | (b) (4) | |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

Height

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 17:32:05 |
| Query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' answered with 'done' (Site from DM). | Meghan York (b) (4) | 29 Sep 2020 15:25:55 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 29 Sep 2020 15:25:51 |
| User opened query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM). | (b) (4), (b) (6) | 03 Sep 2020 15:13:52 |
| User entered '71' in | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

Weight

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Sep 2020 15:25:51 |
| User entered '154.0' lb | Meghan York (b) (4) | 28 Aug 2020 20:05:03 |
| | Jami Wagner (b) (4) | |
| | (b) (4) | |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Jami Wagner (b) (4) (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '10:25' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '26 Aug 2020 10:25' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '98.5' F | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Other (Other)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Temporal' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '84' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'bpm' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '12' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'breaths/min' | System | 28 Aug 2020 20:05:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '126' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 28 Aug 2020 20:05:03 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '78' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

Height

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 17:32:05 |
| Query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' answered with 'done' (Site from DM). | Meghan York (b) (4) | 29 Sep 2020 15:25:55 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 29 Sep 2020 15:25:51 |
| User opened query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM). | (b) (4), (b) (6) | 03 Sep 2020 15:13:52 |
| User entered '71' in | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

Weight

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 29 Sep 2020 15:25:51 |
| User entered '154.0' lb | Meghan York (b) (4) | 28 Aug 2020 20:05:03 |
| | Jami Wagner (b) (4) | |
| | (b) (4) | |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Jami Wagner (b) (4) (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '11:30' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '26 Aug 2020 11:30' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '98.4' F | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Other (Other)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Temporal' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '54' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'bpm' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '14' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'breaths/min' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '128' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '73' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 28 Aug 2020 20:05:03 |

US3142255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 29 Sep 2020 15:26:06 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Jami Wagner (b) (4) | 28 Aug 2020 20:05:13 |
| | (b) (4) | |

US3142255

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty; reason for change Data Entry Error | (b) (4) Meghan York (b) (4) | 29 Sep 2020 15:26:06 |
| User entered '26 Aug 2020' | (b) (4) Jami Wagner (b) (4) | 28 Aug 2020 20:05:13 |
| | (b) (4) | |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

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) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Shelby Pickle (b) (4) | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '11:00' | (b) (4) Shelby Pickle (b) (4) | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '26 Aug 2020 11:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Left Arm (LEFT ARM)' | Shelby Pickle (b) (4) | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'ONCE' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'INTRAMUSCULAR' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:33 |

US3142255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:33 |

US3142255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '10:39' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:33 |

US3142255

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '26 Aug 2020 10:39' | System | 28 Aug 2020 20:05:33 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:04:27

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '26 Aug 2020' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Jami Wagner (b) (4) (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '10:39' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '26 Aug 2020 10:39' | System | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Jami Wagner (b) (4) (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '10:39' | Jami Wagner (b) (4) | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '26 Aug 2020 10:39' | System | 28 Aug 2020 20:05:49 |

US3142255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) | 26 Aug 2020 17:35:15 |

US3142255

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 26 Aug 2020 17:35:15 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 11:20' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 13:50' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 14:45' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 2' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 3' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 4' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 5' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '31 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 6' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '31 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '01 Sep 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 7' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '01 Sep 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '02 Sep 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 11:20' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 13:50' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 14:45' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 2' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 3' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 4' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 5' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '31 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 6' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '31 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '01 Sep 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 7' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:07:27', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '3eda4c5b-b243-40c2-b830-6f7d4d654cf1' | System | 02 Sep 2020 12:07:38 |
| User entered 'Does not interfere with activity (2)' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:07:12', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '3eda4c5b-b243-40c2-b830-6f7d4d654cf1' User entered 'No (N)' | System | 02 Sep 2020 12:07:38 |
| | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:07:15', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '3eda4c5b-b243-40c2-b830-6f7d4d654cf1' User entered 'No (N)' | System | 02 Sep 2020 12:07:38 |
| | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:07:21', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '3eda4c5b-b243-40c2-b830-6f7d4d654cf1' User entered 'None (1)' | System | 02 Sep 2020 12:07:38 |
| | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:07:35', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '3eda4c5b-b243-40c2-b830-6f7d4d654cf1' User entered '02 Sep 2020 06:07' | System | 02 Sep 2020 12:07:38 |
| | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '01 Sep 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '02 Sep 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 11:20' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 13:50' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Aug 2020 14:45' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 2' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 3' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 4' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 5' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '31 Aug 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 6' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '31 Aug 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '01 Sep 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 7' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:01', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'None (0)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:04', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'None (0)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:07', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'None (0)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:21', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'None (0)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:26', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'None (0)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:28', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'None (0)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:35', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered 'No (N)' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-02T06:08:38', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '39b855c6-4554-4cad-953c-a4200088eed5' User entered '02 Sep 2020 06:08' | System | 02 Sep 2020 12:08:42 |
| | System | 02 Sep 2020 12:08:42 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '01 Sep 2020 12:00' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '02 Sep 2020 11:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 02 Sep 2020 12:07:38 |
| User entered 'Day 8' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '02 Sep 2020 12:00' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 02 Sep 2020 12:07:38 |
| User entered 'Day 9' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 02 Sep 2020 12:07:38 |
| User entered 'Day 8' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '02 Sep 2020 12:00' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 02 Sep 2020 12:07:38 |
| User entered 'Day 9' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 12:07:38 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 10 Sep 2020 16:41:40 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 18 Sep 2020 15:57:56 |
| Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct' (Site from System). | Jami Wagner (b) (4) | 10 Sep 2020 16:41:48 |
| User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 10 Sep 2020 16:41:40 |
| User entered '08 Sep 2020' | Jami Wagner (b) (4) | 10 Sep 2020 16:41:40 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 10 Sep 2020 16:41:40 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 10 Sep 2020 16:41:40 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 10 Sep 2020 16:41:54 |

US3142255

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 10 Sep 2020 16:41:54 |

US3142255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) | 11 Nov 2020 16:41:07 |

US3142255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 05:18:06 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Information provided is correct per source document' (Site from System). | Shelby Pickle (b) (4) (b) (4) | 11 Nov 2020 16:44:05 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 11 Nov 2020 16:41:07 |
| User entered '14 Sep 2020' | Shelby Pickle (b) (4) (b) (4) | 11 Nov 2020 16:41:07 |

US3142255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Shelby Pickle (b) (4) | 11 Nov 2020 16:41:07 |

US3142255

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | (b) (4) Shelby Pickle (b) (4) | 11 Nov 2020 16:41:07 |

US3142255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 23 Sep 2020 15:24:44 |

US3142255

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 23 Sep 2020 15:24:44 |

US3142255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Dalia Jeronimo (b) (4) | 24 Sep 2020 18:31:17 |

US3142255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '17 Sep 2020' | Dalia Jeronimo (b) (4) | 24 Sep 2020 18:31:17 |

US3142255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Dalia Jeronimo (b) (4) | 24 Sep 2020 18:31:17 |

US3142255

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Dalia Jeronimo (b) (4) | 24 Sep 2020 18:31:17 |

US3142255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 23 Sep 2020 15:24:59 |

US3142255

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 23 Sep 2020 15:24:59 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:29:23 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23 Sep 2020' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:29:23 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Clinic (Clinic)' | Shelby Pickle (b) (4) | 23 Sep 2020 17:29:23 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'VISIT2' | System | 23 Sep 2020 17:29:23 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Shelby Pickle (b) (4) (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23 Sep 2020' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '08:36' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '23 Sep 2020 08:36' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '98.0' F | Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Other (Other)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Temporal' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '82' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'bpm' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '14' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'breaths/min' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '127' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '77' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Shelby Pickle (b) (4) (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23 Sep 2020' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '09:50' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '23 Sep 2020 09:50' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '98.9' F | Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Other (Other)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Temporal' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '70' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'bpm' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '12' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'breaths/min' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '110' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '83' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 23 Sep 2020 17:30:39 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:02 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23 Sep 2020' | Shelby Pickle (b) (4) | 23 Sep 2020 17:31:02 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

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) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23 Sep 2020' | Jami Wagner (b) (4) | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '09:19' | Jami Wagner (b) (4) | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '23 Sep 2020 09:19' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Left Arm (LEFT ARM)' | Jami Wagner (b) (4) | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'ONCE' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'INTRAMUSCULAR' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:17 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 23SEP2020; however it is recorded in EDC for Visit 2 Day 29. Please confirm collection date of 23SEP2020 is for Visit 2 Day 29 or else clarify. ' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 07:04:54 |
| Query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 23SEP2020; however it is recorded in EDC for Visit 2 Day 29. Please confirm collection date of 23SEP2020 is for Visit 2 Day 29 or else clarify. | Meghan York (b) (4) | 19 Oct 2020 20:46:27 |
| ' answered with 'Unschedlued lab kit was used for this visit due to lack of supplies ' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 01:14:06 |
| User opened query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 23SEP2020; however it is recorded in EDC for Visit 2 Day 29. Please confirm collection date of 23SEP2020 is for Visit 2 Day 29 or else clarify. ' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 01:13:51 |
| Query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 23SEP2020; however it is recorded in EDC for Visit 3 Day 57. Please confirm collection date of 23SEP2020 is for Visit 2 Day 29 or else clarify. ' canceled (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 01:01:52 |
| User opened query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 23SEP2020; however it is recorded in EDC for Visit 3 Day 57. Please confirm collection date of 23SEP2020 is for Visit 2 Day 29 or else clarify. ' (Site from DM). | (b) (4), (b) (6) | |
| User entered '23 Sep 2020' | Shelby Pickle (b) (4) | 23 Sep 2020 17:31:17 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '08:55' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:17 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '23 Sep 2020 08:55' | System | 23 Sep 2020 17:31:17 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:04:27

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 23SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 27 Nov 2020 08:26:16 |
| Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 23SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' answered with 'Information is correct. Unscheduled lab kit was used for this visit due to lack of supplies ' (Site from DM). | Meghan York (b) (4) (b) (4) | 23 Oct 2020 16:49:19 |
| User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 23SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please review and confirm the Correct Visit and update as appropriate. Else Clarify, Thank you.' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 00:13:08 |
| User entered '23 Sep 2020' | Shelby Pickle (b) (4) (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Shelby Pickle (b) (4) (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '08:50' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '23 Sep 2020 08:50' | System | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Shelby Pickle (b) (4) (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '08:50' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '23 Sep 2020 08:50' | System | 23 Sep 2020 17:31:31 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 23 Sep 2020 17:31:37 |

US3142255

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '1' | System | 23 Sep 2020 17:31:37 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:04', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4dbe94ff-c785-481b-9324-4067b045b9b6' User entered 'Yes (Y)' | System | 23 Sep 2020 15:50:25 |
| | System | 23 Sep 2020 15:50:25 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:13', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4dbe94ff-c785-481b-9324-4067b045b9b6' User entered '98.9' | System | 23 Sep 2020 15:50:25 |
| | System | 23 Sep 2020 15:50:25 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:18', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4dbe94ff-c785-481b-9324-4067b045b9b6' | System | 23 Sep 2020 15:50:25 |
| User entered 'No (N)' | System | 23 Sep 2020 15:50:25 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:21', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4dbe94ff-c785-481b-9324-4067b045b9b6' User entered '23 Sep 2020 09:50' | System | 23 Sep 2020 15:50:25 |
| | System | 23 Sep 2020 15:50:25 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '23 Sep 2020 09:39' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '23 Sep 2020 12:09' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' User entered 'Yes (Y)' | System | 23 Sep 2020 23:24:10 |
| | System | 23 Sep 2020 23:24:10 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:23:59', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' User entered '97.7' | System | 23 Sep 2020 23:24:10 |
| | System | 23 Sep 2020 23:24:10 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:24:02', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' | System | 23 Sep 2020 23:24:10 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 23:24:10 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted. Medication is now listed on ConMed page.' (Site from System). | (b) (4), (b) (6) | 17 Nov 2020 02:30:54 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:24:05', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' User entered '1' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:43:23 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 23 Sep 2020 23:24:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:24:05', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' User entered '1' | System | 23 Sep 2020 23:24:10 |
| User entered '1' | System | 23 Sep 2020 23:24:10 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:24:05', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' User entered '0' | System | 23 Sep 2020 23:24:10 |
| | System | 23 Sep 2020 23:24:10 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:24:08', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '48b724a6-0800-4e06-a109-4c0d378d5078' | System | 23 Sep 2020 23:24:10 |
| User entered '23 Sep 2020 17:24' | System | 23 Sep 2020 23:24:10 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '23 Sep 2020 13:04' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '24 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 2' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 3' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:17', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '07d1321f-4216-4a0b-b8bc-2d06f3f1246c' User entered 'Yes (Y)' | System | 25 Sep 2020 20:17:31 |
| | System | 25 Sep 2020 20:17:31 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:22', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '07d1321f-4216-4a0b-b8bc-2d06f3f1246c' User entered '97.8' | System | 25 Sep 2020 20:17:31 |
| | System | 25 Sep 2020 20:17:31 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:24', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '07d1321f-4216-4a0b-b8bc-2d06f3f1246c' User entered 'No (N)' | System | 25 Sep 2020 20:17:31 |
| | System | 25 Sep 2020 20:17:31 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:29', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '07d1321f-4216-4a0b-b8bc-2d06f3f1246c' User entered '25 Sep 2020 14:17' | System | 25 Sep 2020 20:17:31 |
| | System | 25 Sep 2020 20:17:31 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '25 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '26 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 4' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:27', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bd35c5e7-833e-4464-8c30-0726e33130fa' User entered 'Yes (Y)' | System | 27 Sep 2020 03:28:38 |
| | System | 27 Sep 2020 03:28:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:31', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bd35c5e7-833e-4464-8c30-0726e33130fa' User entered '97.7' | System | 27 Sep 2020 03:28:38 |
| | System | 27 Sep 2020 03:28:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:33', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bd35c5e7-833e-4464-8c30-0726e33130fa' User entered 'No (N)' | System | 27 Sep 2020 03:28:38 |
| | System | 27 Sep 2020 03:28:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:35', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bd35c5e7-833e-4464-8c30-0726e33130fa' User entered '26 Sep 2020 21:28' | System | 27 Sep 2020 03:28:38 |
| | System | 27 Sep 2020 03:28:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '26 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '27 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 5' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:28', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bc324898-c780-49d5-8580-ba5e9ce151a3' User entered 'Yes (Y)' | System | 28 Sep 2020 12:18:38 |
| | System | 28 Sep 2020 12:18:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:32', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bc324898-c780-49d5-8580-ba5e9ce151a3' User entered '97.7' | System | 28 Sep 2020 12:18:38 |
| | System | 28 Sep 2020 12:18:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:33', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bc324898-c780-49d5-8580-ba5e9ce151a3' | System | 28 Sep 2020 12:18:38 |
| User entered 'No (N)' | System | 28 Sep 2020 12:18:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:35', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'bc324898-c780-49d5-8580-ba5e9ce151a3' User entered '28 Sep 2020 06:18' | System | 28 Sep 2020 12:18:38 |
| | System | 28 Sep 2020 12:18:38 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '27 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '28 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 6' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '28 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '29 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 7' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '29 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '30 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:26', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '22f6e2cc-13a8-46d5-b636-6da5ee471479' | System | 23 Sep 2020 15:50:42 |
| User entered 'None (1)' | System | 23 Sep 2020 15:50:42 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:30', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '22f6e2cc-13a8-46d5-b636-6da5ee471479' User entered 'No (N)' | System | 23 Sep 2020 15:50:42 |
| | System | 23 Sep 2020 15:50:42 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:32', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '22f6e2cc-13a8-46d5-b636-6da5ee471479' User entered 'No (N)' | System | 23 Sep 2020 15:50:42 |
| | System | 23 Sep 2020 15:50:42 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:37', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '22f6e2cc-13a8-46d5-b636-6da5ee471479' | System | 23 Sep 2020 15:50:42 |
| User entered 'None (1)' | System | 23 Sep 2020 15:50:42 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:39', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '22f6e2cc-13a8-46d5-b636-6da5ee471479' User entered '23 Sep 2020 09:50' | System | 23 Sep 2020 15:50:42 |
| | System | 23 Sep 2020 15:50:42 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '23 Sep 2020 09:39' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '23 Sep 2020 12:09' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:08', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c838f9f4-99af-4b76-b37c-de36d0b23428' | System | 23 Sep 2020 23:20:41 |
| User entered 'None (1)' | System | 23 Sep 2020 23:20:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:23', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c838f9f4-99af-4b76-b37c-de36d0b23428' User entered 'No (N)' | System | 23 Sep 2020 23:20:41 |
| | System | 23 Sep 2020 23:20:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:29', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c838f9f4-99af-4b76-b37c-de36d0b23428' User entered 'No (N)' | System | 23 Sep 2020 23:20:41 |
| | System | 23 Sep 2020 23:20:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:33', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c838f9f4-99af-4b76-b37c-de36d0b23428' | System | 23 Sep 2020 23:20:41 |
| User entered 'None (1)' | System | 23 Sep 2020 23:20:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:38', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c838f9f4-99af-4b76-b37c-de36d0b23428' User entered '23 Sep 2020 17:20' | System | 23 Sep 2020 23:20:41 |
| | System | 23 Sep 2020 23:20:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '23 Sep 2020 13:04' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '24 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 2' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 3' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:31', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '7b8b89f8-8506-43f7-a158-20bcb77ef9c5' | System | 25 Sep 2020 20:17:41 |
| User entered 'None (1)' | System | 25 Sep 2020 20:17:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:33', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '7b8b89f8-8506-43f7-a158-20bcb77ef9c5' User entered 'No (N)' | System | 25 Sep 2020 20:17:41 |
| | System | 25 Sep 2020 20:17:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:34', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '7b8b89f8-8506-43f7-a158-20bcb77ef9c5' | System | 25 Sep 2020 20:17:41 |
| User entered 'No (N)' | System | 25 Sep 2020 20:17:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:36', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '7b8b89f8-8506-43f7-a158-20bcb77ef9c5' | System | 25 Sep 2020 20:17:41 |
| User entered 'None (1)' | System | 25 Sep 2020 20:17:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:37', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '7b8b89f8-8506-43f7-a158-20bcb77ef9c5' User entered '25 Sep 2020 14:17' | System | 25 Sep 2020 20:17:41 |
| | System | 25 Sep 2020 20:17:41 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '25 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '26 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 4' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:38', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '630eb4f3-adc6-4d61-98f7-8264248f9bab' | System | 27 Sep 2020 03:28:47 |
| User entered 'None (1)' | System | 27 Sep 2020 03:28:47 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:39', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '630eb4f3-adc6-4d61-98f7-8264248f9bab' User entered 'No (N)' | System | 27 Sep 2020 03:28:47 |
| | System | 27 Sep 2020 03:28:47 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:41', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '630eb4f3-adc6-4d61-98f7-8264248f9bab' User entered 'No (N)' | System | 27 Sep 2020 03:28:47 |
| | System | 27 Sep 2020 03:28:47 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:42', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '630eb4f3-adc6-4d61-98f7-8264248f9bab' User entered 'None (1)' | System | 27 Sep 2020 03:28:47 |
| | System | 27 Sep 2020 03:28:47 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '630eb4f3-adc6-4d61-98f7-8264248f9bab' User entered '26 Sep 2020 21:28' | System | 27 Sep 2020 03:28:47 |
| | System | 27 Sep 2020 03:28:47 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '26 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '27 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 5' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:39', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5e0a5a6b-cead-4f86-9b2f-348f789f4c14' User entered 'None (1)' | System | 28 Sep 2020 12:18:46 |
| | System | 28 Sep 2020 12:18:46 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:40', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5e0a5a6b-cead-4f86-9b2f-348f789f4c14' User entered 'No (N)' | System | 28 Sep 2020 12:18:46 |
| | System | 28 Sep 2020 12:18:46 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:41', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5e0a5a6b-cead-4f86-9b2f-348f789f4c14' User entered 'No (N)' | System | 28 Sep 2020 12:18:46 |
| | System | 28 Sep 2020 12:18:46 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:42', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5e0a5a6b-cead-4f86-9b2f-348f789f4c14' User entered 'None (1)' | System | 28 Sep 2020 12:18:46 |
| | System | 28 Sep 2020 12:18:46 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5e0a5a6b-cead-4f86-9b2f-348f789f4c14' User entered '28 Sep 2020 06:18' | System | 28 Sep 2020 12:18:46 |
| | System | 28 Sep 2020 12:18:46 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '27 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '28 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 6' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '28 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '29 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 7' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '29 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| User entered '30 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:42', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'None (0)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'None (0)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'None (0)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:48', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'None (0)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:51', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'None (0)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:52', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'None (0)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:56', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered 'No (N)' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T09:50:58', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e54d53fc-a96a-4a16-9462-624422db1294' User entered '23 Sep 2020 09:50' | System | 23 Sep 2020 15:51:01 |
| | System | 23 Sep 2020 15:51:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '23 Sep 2020 09:39' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '23 Sep 2020 12:09' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:19:41', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' | System | 23 Sep 2020 23:20:06 |
| User entered 'No interference with activity (1)' | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:19:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' User entered 'None (0)' | System | 23 Sep 2020 23:20:06 |
| | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:19:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' User entered 'None (0)' | System | 23 Sep 2020 23:20:06 |
| | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:19:47', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' User entered 'None (0)' | System | 23 Sep 2020 23:20:06 |
| | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:19:50', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' | System | 23 Sep 2020 23:20:06 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)' | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:19:52', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' User entered 'None (0)' | System | 23 Sep 2020 23:20:06 |
| | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:01', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' User entered 'No (N)' | System | 23 Sep 2020 23:20:06 |
| | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-23T17:20:03', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '597d6bb0-7c39-4100-a019-2462b477091d' User entered '23 Sep 2020 17:20' | System | 23 Sep 2020 23:20:06 |
| | System | 23 Sep 2020 23:20:06 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '23 Sep 2020 13:04' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '24 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 2' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '24 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '25 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 3' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:40', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'None (0)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:41', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'None (0)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:42', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'None (0)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:43', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'None (0)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:45', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'None (0)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'None (0)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:49', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered 'No (N)' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-25T14:17:51', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557a207c-aa26-45c8-a5e8-111fb4d8e8d2' User entered '25 Sep 2020 14:17' | System | 25 Sep 2020 20:17:54 |
| | System | 25 Sep 2020 20:17:54 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '25 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 4' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:49', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered 'None (0)' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:50', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered 'None (0)' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:52', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered 'None (0)' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:54', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered 'None (0)' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:55', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered 'None (0)' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:56', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered 'None (0)' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:28:58', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' | System | 27 Sep 2020 03:29:01 |
| User entered 'No (N)' | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-26T21:29:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '322cef66-a4fa-4489-b57e-96a92a018da3' User entered '26 Sep 2020 21:29' | System | 27 Sep 2020 03:29:01 |
| | System | 27 Sep 2020 03:29:01 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '26 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 5' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:47', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'None (0)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:48', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'None (0)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:49', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'None (0)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:51', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'None (0)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:52', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'None (0)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:53', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'None (0)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:55', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered 'No (N)' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-09-28T06:18:56', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b3201441-9a4d-4071-801e-934359ef1085' User entered '28 Sep 2020 06:18' | System | 28 Sep 2020 12:18:59 |
| | System | 28 Sep 2020 12:18:59 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '27 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 6' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '28 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| Data entry locked. | System | 23 Sep 2020 15:25:44 |
| User entered 'Day 7' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| | | |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '29 Sep 2020 12:00' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:27

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:02:35 |
| User entered '30 Sep 2020 11:59' | System | 23 Sep 2020 15:25:44 |

US3142255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 06 Oct 2020 16:48:16 |

US3142255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '30 Sep 2020' | Jami Wagner (b) (4) | 06 Oct 2020 16:48:16 |

US3142255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 06 Oct 2020 16:48:16 |

US3142255

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 06 Oct 2020 16:48:16 |

US3142255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 06 Oct 2020 16:48:22 |

US3142255

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 06 Oct 2020 16:48:22 |

US3142255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Dalia Jeronimo (b) (4) | 08 Oct 2020 15:28:53 |

US3142255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '7 Oct 2020' | Dalia Jeronimo (b) (4) | 08 Oct 2020 15:28:53 |

US3142255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Dalia Jeronimo (b) (4) | 08 Oct 2020 15:28:53 |

US3142255

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Dalia Jeronimo (b) (4) | 08 Oct 2020 15:28:53 |

US3142255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Dalia Jeronimo (b) (4) | 08 Oct 2020 15:29:03 |

US3142255

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 08 Oct 2020 15:29:03 |

US3142255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Dalia Jeronimo (b) (4) | 20 Oct 2020 19:43:21 |

US3142255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '15 Oct 2020' | Dalia Jeronimo (b) (4) | 20 Oct 2020 19:43:21 |

US3142255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Dalia Jeronimo (b) (4) | 20 Oct 2020 19:43:21 |

US3142255

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Dalia Jeronimo (b) (4) | 20 Oct 2020 19:43:21 |

US3142255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Dalia Jeronimo (b) (4) | 20 Oct 2020 19:43:11 |

US3142255

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'I' | System | 20 Oct 2020 19:43:11 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) | 21 Oct 2020 16:43:46 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '21 Oct 2020' | Shelby Pickle (b) (4) | 21 Oct 2020 16:43:46 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Clinic (Clinic)' | Shelby Pickle (b) (4) | 21 Oct 2020 16:43:46 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'VISIT3' | System | 21 Oct 2020 16:43:46 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '21 Oct 2020' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '09:17' | Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '21 Oct 2020 09:17' | System | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '98.2' F | Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Other (Other)' | Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Temporal' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '55' | Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'bpm' | System | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '12' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'breaths/min' | System | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '125' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '73' | Shelby Pickle (b) (4) | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered 'mmHg' | System | 21 Oct 2020 16:44:15 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| | | |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:24 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '21 Oct 2020' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:24 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:36 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '21 Oct 2020' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:36 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '09:27' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:36 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '21 Oct 2020 09:27' | System | 21 Oct 2020 16:44:36 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) | 21 Oct 2020 16:44:41 |

US3142255

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '1' | System | 21 Oct 2020 16:44:41 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 64' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-10-26T07:18:58', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '141a454b-403a-4336-bd3d-0a010ef6d312' | System | 26 Oct 2020 13:19:06 |
| User entered 'No (N)' | System | 26 Oct 2020 13:19:06 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-10-26T07:19:01', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '141a454b-403a-4336-bd3d-0a010ef6d312' | System | 26 Oct 2020 13:19:06 |
| User entered 'No (N)' | System | 26 Oct 2020 13:19:06 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-10-26T07:19:04', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '141a454b-403a-4336-bd3d-0a010ef6d312' User entered '26 Oct 2020 07:19:04' | System | 26 Oct 2020 13:19:06 |
| | System | 26 Oct 2020 13:19:06 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered '26 Oct 2020 00:01' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered '30 Oct 2020 23:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 71' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-02T09:43:12', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '6732d940-f71e-46f5-b72f-a71eb6406dc7' User entered 'No (N)' | System | 02 Nov 2020 16:43:18 |
| | System | 02 Nov 2020 16:43:18 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-02T09:43:14', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '6732d940-f71e-46f5-b72f-a71eb6406dc7' | System | 02 Nov 2020 16:43:18 |
| User entered 'No (N)' | System | 02 Nov 2020 16:43:18 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-02T09:43:16', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '6732d940-f71e-46f5-b72f-a71eb6406dc7' User entered '02 Nov 2020 09:43:16' | System | 02 Nov 2020 16:43:18 |
| | System | 02 Nov 2020 16:43:18 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered '02 Nov 2020 00:01' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered '06 Nov 2020 23:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered 'Day 78' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-09T05:05:09', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e1593203-1c30-4a72-ba2b-9703fd684204' User entered 'No (N)' | System | 09 Nov 2020 12:05:18 |
| | System | 09 Nov 2020 12:05:18 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-09T05:05:13', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e1593203-1c30-4a72-ba2b-9703fd684204' User entered 'No (N)' | System | 09 Nov 2020 12:05:18 |
| | System | 09 Nov 2020 12:05:18 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-09T05:05:16', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'e1593203-1c30-4a72-ba2b-9703fd684204' User entered '09 Nov 2020 05:05:16' | System | 09 Nov 2020 12:05:18 |
| | System | 09 Nov 2020 12:05:18 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered '09 Nov 2020 00:01' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:04:39 |
| Data entry locked. | System | 26 Aug 2020 17:35:09 |
| User entered '13 Nov 2020 23:59' | System | 26 Aug 2020 17:35:09 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-20T02:28:08', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '8ff86c16-bdf7-4449-a441-3478e697519f' | System | 20 Nov 2020 09:28:57 |
| User entered 'Yes (Y)' | System | 20 Nov 2020 09:28:57 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-20T02:28:15', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '8ff86c16-bdf7-4449-a441-3478e697519f' | System | 20 Nov 2020 09:28:57 |
| User entered 'Yes (Y)' | System | 20 Nov 2020 09:28:57 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Please 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-20T02:28:20', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '8ff86c16-bdf7-4449-a441-3478e697519f' | System | 20 Nov 2020 09:28:57 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 20 Nov 2020 09:28:57 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-20T02:28:32', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '8ff86c16-bdf7-4449-a441-3478e697519f' User entered 'No (N)' | System | 20 Nov 2020 09:28:57 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-20T02:28:40', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '8ff86c16-bdf7-4449-a441-3478e697519f' User entered 'No (N)' | System | 20 Nov 2020 09:28:57 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-20T02:28:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '8ff86c16-bdf7-4449-a441-3478e697519f' User entered '20 Nov 2020 02:28:46' | System | 20 Nov 2020 09:28:57 |
| | System | 20 Nov 2020 09:28:57 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-27T06:21:11', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a5d6dcb7-5930-40fa-b605-f1335553c44c' User entered 'No (N)' | System | 27 Nov 2020 13:21:22 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-27T06:21:14', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a5d6dcb7-5930-40fa-b605-f1335553c44c' | System | 27 Nov 2020 13:21:22 |
| User entered 'No (N)' | System | 27 Nov 2020 13:21:22 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-11-27T06:21:17', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a5d6dcb7-5930-40fa-b605-f1335553c44c' User entered '27 Nov 2020 06:21:17' | System | 27 Nov 2020 13:21:22 |
| | System | 27 Nov 2020 13:21:22 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-04T07:03:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557fef1c-ed8f-4724-83a2-7da01641462d' User entered 'No (N)' | System | 04 Dec 2020 14:03:52 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-04T07:03:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557fef1c-ed8f-4724-83a2-7da01641462d' | System | 04 Dec 2020 14:03:52 |
| User entered 'No (N)' | System | 04 Dec 2020 14:03:52 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-04T07:03:49', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '557fef1c-ed8f-4724-83a2-7da01641462d' User entered '04 Dec 2020 07:03:49' | System | 04 Dec 2020 14:03:52 |
| | System | 04 Dec 2020 14:03:52 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-11T04:28:07', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b34ba09a-594f-41a6-8807-ddb956a57130' User entered 'No (N)' | System | 11 Dec 2020 11:28:14 |
| | System | 11 Dec 2020 11:28:14 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-11T04:28:09', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b34ba09a-594f-41a6-8807-ddb956a57130' User entered 'No (N)' | System | 11 Dec 2020 11:28:14 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-11T04:28:12', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'b34ba09a-594f-41a6-8807-ddb956a57130' User entered '11 Dec 2020 04:28:12' | System | 11 Dec 2020 11:28:14 |
| | System | 11 Dec 2020 11:28:14 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-18T08:21:18', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '70355b71-5f78-452b-83a7-cd5ea253a5e0' User entered 'No (N)' | System | 18 Dec 2020 15:21:28 |
| | System | 18 Dec 2020 15:21:28 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-18T08:21:20', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '70355b71-5f78-452b-83a7-cd5ea253a5e0' User entered 'No (N)' | System | 18 Dec 2020 15:21:28 |
| | System | 18 Dec 2020 15:21:28 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-18T08:21:24', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '70355b71-5f78-452b-83a7-cd5ea253a5e0' User entered '18 Dec 2020 08:21:24' | System | 18 Dec 2020 15:21:28 |
| | System | 18 Dec 2020 15:21:28 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-25T16:00:43', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'cad1c774-90db-4cf7-9864-76d029cd4d4c' User entered 'No (N)' | System | 25 Dec 2020 23:00:49 |
| | System | 25 Dec 2020 23:00:49 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-25T16:00:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'cad1c774-90db-4cf7-9864-76d029cd4d4c' | System | 25 Dec 2020 23:00:49 |
| User entered 'No (N)' | System | 25 Dec 2020 23:00:49 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2020-12-25T16:00:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'cad1c774-90db-4cf7-9864-76d029cd4d4c' User entered '25 Dec 2020 16:00:46' | System | 25 Dec 2020 23:00:49 |
| | System | 25 Dec 2020 23:00:49 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-01T00:14:36', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '6dd9be4b-316d-493a-8802-9ab8906881a1' User entered 'No (N)' | System | 01 Jan 2021 07:14:43 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-01T00:14:38', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '6dd9be4b-316d-493a-8802-9ab8906881a1' | System | 01 Jan 2021 07:14:43 |
| User entered 'No (N)' | System | 01 Jan 2021 07:14:43 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-01T00:14:40', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '6dd9be4b-316d-493a-8802-9ab8906881a1' User entered '01 Jan 2021 00:14:40' | System | 01 Jan 2021 07:14:43 |
| | System | 01 Jan 2021 07:14:43 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-08T18:15:16', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a1cbfc09-7fe4-4f4d-b6d8-b6ebb1169625' | System | 09 Jan 2021 01:15:23 |
| User entered 'No (N)' | System | 09 Jan 2021 01:15:23 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-08T18:15:18', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a1cbfc09-7fe4-4f4d-b6d8-b6ebb1169625' | System | 09 Jan 2021 01:15:23 |
| User entered 'No (N)' | System | 09 Jan 2021 01:15:23 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-08T18:15:20', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a1cbfc09-7fe4-4f4d-b6d8-b6ebb1169625' User entered '08 Jan 2021 18:15:20' | System | 09 Jan 2021 01:15:23 |
| | System | 09 Jan 2021 01:15:23 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-15T06:55:44', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'd316ce88-ef85-4775-abf1-33eaf9477b9' User entered 'No (N)' | System | 15 Jan 2021 13:55:50 |
| | System | 15 Jan 2021 13:55:50 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-15T06:55:46', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'd316ce88-ef85-4775-abf1-33eaf9477b9' | System | 15 Jan 2021 13:55:50 |
| User entered 'No (N)' | System | 15 Jan 2021 13:55:50 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-15T06:55:48', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'd316ce88-ef85-4775-abf1-33eaf9477b9' User entered '15 Jan 2021 06:55:48' | System | 15 Jan 2021 13:55:50 |
| | System | 15 Jan 2021 13:55:50 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-22T10:21:53', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a8d9574b-d5df-4c4e-b62f-c7a9cd04f079' | System | 22 Jan 2021 17:22:06 |
| User entered 'No (N)' | System | 22 Jan 2021 17:22:06 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-22T10:21:55', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a8d9574b-d5df-4c4e-b62f-c7a9cd04f079' | System | 22 Jan 2021 17:22:06 |
| User entered 'No (N)' | System | 22 Jan 2021 17:22:06 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-01-22T10:21:58', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a8d9574b-d5df-4c4e-b62f-c7a9cd04f079' User entered '22 Jan 2021 10:21:58' | System | 22 Jan 2021 17:22:06 |
| | System | 22 Jan 2021 17:22:06 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-08T07:25:11', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'df228dfe-9855-4b32-a29e-8f30bcfbf7a0' User entered 'No (N)' | System | 08 Feb 2021 14:25:17 |
| | System | 08 Feb 2021 14:25:17 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-08T07:25:13', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'df228dfe-9855-4b32-a29e-8f30bcfbf7a0' | System | 08 Feb 2021 14:25:17 |
| User entered 'No (N)' | System | 08 Feb 2021 14:25:17 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-08T07:25:15', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'df228dfe-9855-4b32-a29e-8f30bcfbf7a0' User entered '08 Feb 2021 07:25:15' | System | 08 Feb 2021 14:25:17 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-12T00:01:12', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a2de7cc2-b3e3-45e4-8425-b08f7952abe6' User entered 'No (N)' | System | 12 Feb 2021 07:01:19 |
| | System | 12 Feb 2021 07:01:19 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-12T00:01:13', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a2de7cc2-b3e3-45e4-8425-b08f7952abe6' | System | 12 Feb 2021 07:01:19 |
| User entered 'No (N)' | System | 12 Feb 2021 07:01:19 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-12T00:01:15', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'a2de7cc2-b3e3-45e4-8425-b08f7952abe6' User entered '12 Feb 2021 00:01:15' | System | 12 Feb 2021 07:01:19 |
| | System | 12 Feb 2021 07:01:19 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-26T08:27:09-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '466bd8b4-ecee-4faf-bbbd-b3e0e1611475' User entered 'No (N)' | System | 26 Feb 2021 15:27:17 |
| | System | 26 Feb 2021 15:27:17 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-26T08:27:11-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '466bd8b4-ecee-4faf-bbbd-b3e0e1611475' | System | 26 Feb 2021 15:27:17 |
| User entered 'No (N)' | System | 26 Feb 2021 15:27:17 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-02-26T08:27:14-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '466bd8b4-ecee-4faf-bbbd-b3e0e1611475' User entered '26 Feb 2021 15:27:14' | System | 26 Feb 2021 15:27:17 |
| | System | 26 Feb 2021 15:27:17 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-05T06:53:51-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4d2e711c-cd67-44d5-a1bb-3a1ac987aa20' User entered 'No (N)' | System | 05 Mar 2021 13:54:00 |
| | System | 05 Mar 2021 13:54:00 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-05T06:53:55-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4d2e711c-cd67-44d5-a1bb-3a1ac987aa20' | System | 05 Mar 2021 13:54:00 |
| User entered 'No (N)' | System | 05 Mar 2021 13:54:00 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-05T06:53:57-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '4d2e711c-cd67-44d5-a1bb-3a1ac987aa20' User entered '05 Mar 2021 06:53:57' | System | 05 Mar 2021 13:54:00 |
| | System | 05 Mar 2021 13:54:00 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-12T07:26:01-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '1d55604c-8f33-47d4-81d7-c3eb95b31a23' | System | 12 Mar 2021 14:26:10 |
| User entered 'No (N)' | System | 12 Mar 2021 14:26:10 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-12T07:26:03-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '1d55604c-8f33-47d4-81d7-c3eb95b31a23' | System | 12 Mar 2021 14:26:10 |
| User entered 'No (N)' | System | 12 Mar 2021 14:26:10 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-12T07:26:05-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '1d55604c-8f33-47d4-81d7-c3eb95b31a23' | System | 12 Mar 2021 14:26:10 |
| User entered '12 Mar 2021 07:26:05' | System | 12 Mar 2021 14:26:10 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-19T06:28:15-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5b501e7e-6480-4cca-b795-acc2894928bf' User entered 'No (N)' | System | 19 Mar 2021 12:28:27 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-19T06:28:16-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5b501e7e-6480-4cca-b795-acc2894928bf' User entered 'No (N)' | System | 19 Mar 2021 12:28:27 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-19T06:28:19-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5b501e7e-6480-4cca-b795-acc2894928bf' User entered '19 Mar 2021 06:28:19' | System | 19 Mar 2021 12:28:27 |
| | System | 19 Mar 2021 12:28:27 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-26T07:16:29-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5695828e-d14a-4416-8d3b-ac294cdd6acf' | System | 26 Mar 2021 13:16:36 |
| User entered 'No (N)' | System | 26 Mar 2021 13:16:36 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-26T07:16:30-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5695828e-d14a-4416-8d3b-ac294cdd6acf' | System | 26 Mar 2021 13:16:36 |
| User entered 'No (N)' | System | 26 Mar 2021 13:16:36 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-26T07:16:33-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '5695828e-d14a-4416-8d3b-ac294cdd6acf' User entered '26 Mar 2021 07:16:33' | System | 26 Mar 2021 13:16:36 |
| | System | 26 Mar 2021 13:16:36 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-02T07:11:22-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'd8ac6c82-3308-464d-a6da-a9b71b601ffc' User entered 'No (N)' | System | 07 Apr 2021 23:10:24 |
| | System | 07 Apr 2021 23:10:24 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-02T07:11:23-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'd8ac6c82-3308-464d-a6da-a9b71b601ffc' | System | 07 Apr 2021 23:10:24 |
| User entered 'No (N)' | System | 07 Apr 2021 23:10:24 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-02T07:11:25-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'd8ac6c82-3308-464d-a6da-a9b71b601ffc' | System | 07 Apr 2021 23:10:24 |
| User entered '02 Apr 2021 07:11:25' | System | 07 Apr 2021 23:10:24 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-09T00:02:18-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '82149358-8705-4672-897a-29d14d1c1f9b' | System | 16 Apr 2021 06:09:08 |
| User entered 'No (N)' | System | 16 Apr 2021 06:09:08 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-09T00:02:20-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '82149358-8705-4672-897a-29d14d1c1f9b' | System | 16 Apr 2021 06:09:08 |
| User entered 'No (N)' | System | 16 Apr 2021 06:09:08 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-09T00:02:23-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '82149358-8705-4672-897a-29d14d1c1f9b' | System | 16 Apr 2021 06:09:08 |
| User entered '09 Apr 2021 00:02:23' | System | 16 Apr 2021 06:09:08 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-16T00:09:06-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '06e4bfe9-d0b5-44ee-939c-a59010285c2c' User entered 'No (N)' | System | 16 Apr 2021 06:09:13 |
| | System | 16 Apr 2021 06:09:13 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-16T00:09:07-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '06e4bfe9-d0b5-44ee-939c-a59010285c2c' User entered 'No (N)' | System | 16 Apr 2021 06:09:13 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-16T00:09:10-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '06e4bfe9-d0b5-44ee-939c-a59010285c2c' User entered '16 Apr 2021 00:09:10' | System | 16 Apr 2021 06:09:13 |
| | System | 16 Apr 2021 06:09:13 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-23T03:48:03-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c1a8a709-9a02-4c1f-afc5-ff0c6a7463c2' | System | 23 Apr 2021 09:48:10 |
| User entered 'No (N)' | System | 23 Apr 2021 09:48:10 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-23T03:48:05-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c1a8a709-9a02-4c1f-afc5-ff0c6a7463c2' User entered 'No (N)' | System | 23 Apr 2021 09:48:10 |
| | System | 23 Apr 2021 09:48:10 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-23T03:48:07-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: 'c1a8a709-9a02-4c1f-afc5-ff0c6a7463c2' | System | 23 Apr 2021 09:48:10 |
| User entered '23 Apr 2021 03:48:07' | System | 23 Apr 2021 09:48:10 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-30T00:02:16-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '9cf43aae-a0e9-4b7e-9a2a-eacfe3a0a7e3' User entered 'No (N)' | System | 30 Apr 2021 06:04:24 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

Have you been exposed to someone with 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 (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-30T00:02:17-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '9cf43aae-a0e9-4b7e-9a2a-eacfe3a0a7e3' User entered 'No (N)' | System | 30 Apr 2021 06:04:24 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-04-30T00:02:19-06:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '9cf43aae-a0e9-4b7e-9a2a-eacfe3a0a7e3' User entered '30 Apr 2021 00:02:19' | System | 30 Apr 2021 06:04:24 |
| | System | 30 Apr 2021 06:04:24 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:27

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 18:12:58 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 19 Nov 2020 18:12:58 |

US3142255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:04:27

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:36:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-05T06:54:02-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '05991415-cc6f-421a-a51e-856342d3a3bc' | System | 05 Mar 2021 13:54:09 |
| User entered 'No (N)' | System | 05 Mar 2021 13:54:09 |

US3142255

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:04:27

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:36:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB9A777E-4F7B-4A09-9214-DFADB14E88AC)', Time: '2021-03-05T06:54:07-07:00', User OID: 'PatientReportedOutcome (US3142255)', ODM File OID: '05991415-cc6f-421a-a51e-856342d3a3bc' User entered '05 Mar 2021 06:54:07' | System | 05 Mar 2021 13:54:09 |
| | System | 05 Mar 2021 13:54:09 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 16 Dec 2020 17:24:04 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '16 Nov 2020' | Jami Wagner (b) (4) | 16 Dec 2020 17:24:04 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 16 Dec 2020 17:24:04 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Jami Wagner (b) (4) | 16 Dec 2020 17:24:04 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 16 Dec 2020 18:42:04 |

US3142255

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:51:16 |
| User entered '1' | System | 16 Dec 2020 18:42:04 |

US3142255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 22 Dec 2020 20:46:15 |

US3142255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered '22 Dec 2020' | Jami Wagner (b) (4) | 22 Dec 2020 20:46:15 |

US3142255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 22 Dec 2020 20:46:15 |

US3142255

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered empty. | Jami Wagner (b) (4) | 22 Dec 2020 20:46:15 |

US3142255

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 22 Dec 2020 20:46:20 |

US3142255

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User entered 'I' | System | 22 Dec 2020 20:46:20 |

US3142255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 20:58:33 |
| DataPoint Verified. | | 02 Feb 2021 20:55:44 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) (b) (4) | 19 Jan 2021 00:27:47 |

US3142255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 20:58:35 |
| DataPoint Verified. | | 02 Feb 2021 20:55:44 |
| User entered '18 Jan 2021' | Jami Wagner (b) (4) (b) (4) | 19 Jan 2021 00:27:47 |

US3142255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 20:58:39 |
| DataPoint Verified. | | 02 Feb 2021 20:55:44 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) (b) (4) | 19 Jan 2021 00:27:47 |

US3142255

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| DataPoint Un-verified. | (b) (4) (b) (4), (b) (6) | 02 Feb 2021 20:58:38 |
| DataPoint Verified. | | 02 Feb 2021 20:55:44 |
| User entered empty. | Jami Wagner (b) (4) (b) (4) | 19 Jan 2021 00:27:47 |

US3142255

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:39:31 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 19 Jan 2021 00:27:56 |

US3142255

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User entered '1' | System | 19 Jan 2021 00:27:56 |

US3142255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 23 Feb 2021 22:49:05 |

US3142255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '23 Feb 2021' | Lisa Jackson (b) (4) | 23 Feb 2021 22:49:05 |

US3142255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Lisa Jackson (b) (4) | 23 Feb 2021 22:49:05 |

US3142255

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Lisa Jackson (b) (4) | 23 Feb 2021 22:49:05 |

US3142255

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 23 Feb 2021 22:48:33 |

US3142255

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:36:39 |
| User entered 'I' | System | 23 Feb 2021 22:48:33 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:59:14 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4) (b) (4), (b) (6) | 17 Apr 2021 04:40:41 |
| Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'DATA IS AS DOCUMENTED' (Site from System). | Lisa Jackson (b) (4) (b) (4) | 07 Apr 2021 22:59:53 |
| User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 07 Apr 2021 22:59:14 |
| User entered '07 Apr 2021' | Lisa Jackson (b) (4) (b) (4) | 07 Apr 2021 22:59:14 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:59:14 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 07 Apr 2021 22:59:14 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered 'No (N)' | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 23:00:23 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 23:00:23 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Lisa Jackson (b) (4) (b) (4) | 07 Apr 2021 23:00:23 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 23:00:23 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 23:00:23 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:23 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 23:00:23 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered 'No (N)' | Lisa Jackson (b) (4) | 07 Apr 2021 23:00:36 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | Lisa Jackson (b) (4) (b) (4) | 07 Apr 2021 23:00:36 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 23:01:03 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered '07 Apr 2021' | Lisa Jackson (b) (4) | 07 Apr 2021 23:01:03 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered '16:46' | Lisa Jackson (b) (4) | 07 Apr 2021 23:01:03 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 16:46' | System | 07 Apr 2021 23:01:03 |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 23:01:13 |
| | (b) (4) | |

US3142255

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Apr 2021 23:01:13 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:04:27

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:08:56 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:02 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:39:02 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:04:27

[Time of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:08:56 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 15:30:06 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 23 Nov 2020 04:56:15 |
| Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System). | Shelby Pickle (b) (4) | 20 Nov 2020 17:39:07 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 17:39:02 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:39:02 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:04:27

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:08:56 |
| User entered empty. | System | 20 Nov 2020 17:39:02 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:04:27

[Type of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:08:56 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:06 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:39:02 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:04:27

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:08:56 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:06 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:39:02 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 1 (Day 1)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '13 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:43:30 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 2 (Day 2)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '14 Nov 2020' | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:44:16 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 3 (Day 3)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '15 Nov 2020' | Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:45:04 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 4 (Day 4)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '98' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '98.2' F | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:47:34 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 5 (Day 5)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '17 Nov 2020' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '97' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '99.0' F | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:49:10 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 6 (Day 6)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '18 Nov 2020' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '95' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '99.4' F | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Severe (Severe)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Severe (Severe)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:54:40 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 7 (Day 7)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '19 Nov 2020' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '96' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '99.6' F | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Severe (Severe)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Severe (Severe)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:05 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 8 (Day 8)' | (b) (4) Shelby Pickle (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| Query 'Please provide SD for visits 21-22 Nov 2020' canceled (Site from CRA). | (b) (4) | 24 Nov 2020 15:30:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:24:55 |
| User opened query 'Please provide SD for visits 21-22 Nov 2020' (Site from CRA). | | 23 Nov 2020 22:24:38 |
| Query 'Please enter data for this visit and provide SD for 20-23Nov visits' canceled (Site from CRA). | | 23 Nov 2020 22:23:39 |
| DataPoint Un-verified. | | 23 Nov 2020 22:23:01 |
| User opened query 'Please enter data for this visit and provide SD for 20-23Nov visits' (Site from CRA). | | 23 Nov 2020 22:21:25 |
| Query 'Please enter data for this visit and Nov 21-22 and provide SD. | | 23 Nov 2020 22:19:46 |
| ' canceled (Site from CRA). | | |
| User opened query 'Please enter data for this visit and Nov 21-22 and provide SD. | | 23 Nov 2020 22:18:14 |
| ' (Site from CRA). | | |
| User closed query 'Please reconcile and enter 21-22Nov2020' (Site from CRA). | | 23 Nov 2020 22:13:33 |
| DataPoint Verified. | | 23 Nov 2020 22:04:33 |
| Query 'Please reconcile and enter 21-22Nov2020' answered with 'Will provide' (Site from CRA). | Shelby Pickle (b) (4) | 23 Nov 2020 18:17:35 |
| User opened query 'Please reconcile and enter 21-22Nov2020' (Site from CRA). | (b) (4) | |
| User entered '20 Nov 2020' | (b) (4), (b) (6) | 23 Nov 2020 17:09:22 |
| | Shelby Pickle (b) (4) | 20 Nov 2020 18:14:17 |
| | (b) (4) | |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:12 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:24:55 |
| DataPoint Un-verified. | | 23 Nov 2020 22:23:03 |
| DataPoint Verified. | | 23 Nov 2020 22:04:33 |
| User entered '1' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:15 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered '97' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:24:55 |
| DataPoint Un-verified. | | 23 Nov 2020 22:23:05 |
| DataPoint Verified. | | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 03 Feb 2021 00:36:12 |
| User entered empty. | System | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:29:17 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered '97.5' F reason for change: Data Entry Error | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:20 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:22 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:29 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:50 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:53 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:58 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:29:56 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:30:14 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:16 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Severe (Severe)' reason for change: | (b) (4) | |
| Data Entry Error | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 18:14:17 |
| | (b) (4) | |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:20 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'Severe (Severe)' reason for change: | (b) (4) | |
| Data Entry Error | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 18:14:17 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:21 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:25 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:27 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:29 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:34 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:30:37 |
| DataPoint Un-verified. | Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:36:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:14:17 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 9 (Day 9)' | (b) (4) Shelby Pickle (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '21 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '96' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '99.2' F | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Severe (Severe)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Severe (Severe)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:18:52 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 10 (Day 10)' | (b) (4) Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '22 Nov 2020' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '96' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '98.8' F | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:20:03 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 11 (Day 11)' | (b) (4) Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '23 Nov 2020' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '0' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '98' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered '97.6' F | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 22:04:33 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 18:21:12 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 12 (Day 12)' | (b) (4) Shelby Pickle (b) (4) | 01 Dec 2020 01:42:32 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '24 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '97' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '97.9' F | Shelby Pickle (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:42:32 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 13 (Day 13)' | (b) (4) Shelby Pickle (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '25 Nov 2020' | Shelby Pickle (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '97' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '98.0' F | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Moderate (Moderate)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:44:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 14 (Day 14)' | (b) (4) Shelby Pickle (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '26 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'I' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered empty. | System | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:29 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 15 (Day 15)' | (b) (4) Shelby Pickle (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '27 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'I' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered empty. | System | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:46:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 16 (Day 16)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '28 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '98' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '97.4' F | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'Mild (Mild)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 01 Dec 2020 01:48:47 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 17 (Day 17)' | (b) (4) Shelby Pickle (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '29 Nov 2020' | Shelby Pickle (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'I' | Shelby Pickle (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered empty. | System | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:49:56 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 18 (Day 18)' | (b) (4) Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '30 Nov 2020' | Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'I' | Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered empty. | System | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 01 Dec 2020 01:50:11 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 19 (Day 19)' | (b) (4) Shelby Pickle (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '01 Dec 2020' | Shelby Pickle (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '98' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '98.2' F | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 02 Dec 2020 22:44:51 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Day 21 (Day 21)' | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '07 Dec 2020' | Shelby Pickle (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '98' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User entered '%' | System | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered '97.4' F | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:04:27

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:38:11 |
| User entered 'None (None)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:37:55 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| 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). | | 23 Nov 2020 04:55:44 |
| 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 'Correct. patient is positive for COVID_19' (Site from System). | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:54 |
| 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 | 20 Nov 2020 17:56:39 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[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) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:39 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:56:39 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 15:31:57 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:56:39 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:04:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:11 |
| User entered 'I' | System | 20 Nov 2020 17:56:39 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

Did the subject have Respiratory Rates ≥ 30 per Minute?

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

Did the subject have Heart Rate \geq 125 beats per minute

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

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) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Oxygen Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[PaO2](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Did the subject have Respiratory failure?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

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[High-Flow Oxygen?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Non-Invasive Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Mechanical Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[ECMO?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User closed query 'Please reconcile as illness visit Day 1 vitals diastolic BP was 59mmHg on 16Nov2020' (Site from CRA). | (b) (4) | 24 Nov 2020 00:28:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| Query 'Please reconcile as illness visit Day 1 vitals diastolic BP was 59mmHg on 16Nov2020' answered with 'CHanged, NCS' (Site from CRA). | Shelby Pickle (b) (4) | 23 Nov 2020 21:28:16 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 23 Nov 2020 21:28:08 |
| User opened query 'Please reconcile as illness visit Day 1 vitals diastolic BP was 59mmHg on 16Nov2020' (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 22:39:50 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered '16 Nov 2020' reason for change: Data Entry Error | Shelby Pickle (b) (4) | 23 Nov 2020 21:28:08 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered '16 Nov 2020' reason for change: Data Entry Error | Shelby Pickle (b) (4) | 23 Nov 2020 21:28:08 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Evidence of Shock Requires
Vasopressors](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Acute Renal Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Hepatic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Neurologic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Clinical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

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[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Radiographical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

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[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

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Generated On: 11 Aug 2021 22:04:27

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

US3142255

Folder: Covid-19 Assessment 16 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:04:27

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:09:17 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:28:26 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:57:59 |

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Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:04:27

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:10:04 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:21:34 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:58:06 |

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|---------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:04:27

[Visit](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------|----------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:04:27

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:59:54 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | Shelby Pickle (b) (4) | 03 Feb 2021 00:42:32 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| Query 'Please enter Illness visit and all telemedicine visits into EDC' canceled (Site from CRA). | (b) (4) | 21 Apr 2021 21:01:57 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 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) | 09 Apr 2021 09:13:04 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 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 'You are correct. 17DEC2020 is Convalescence Visit Day 28, in which, at the site, shows no symptoms of COVID. Therefore no Saliva samples were taken for day 3-28.' (Site from DM). | Lisa Jackson (b) (4) | 08 Apr 2021 21:47:35 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 06:23:11 |
| User opened query 'Please enter Illness visit and all telemedicine visits into EDC' (Site from CRA). | | 02 Feb 2021 21:16:33 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 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). | | 08 Jan 2021 15:58:49 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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) | 29 Dec 2020 09:03:09 |
| User closed query 'Please reconcile and enter saliva page' (Site from CRA). | | 24 Nov 2020 22:11:50 |
| Query 'Please reconcile and enter saliva page' answered with 'site unable to complete as subject has not yet returned to clinic to return saliva samples' (Site from CRA). | Jill York (b) (4) | 24 Nov 2020 21:45:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:22:31 |
| User opened query 'Please reconcile and enter saliva page' (Site from CRA). | | 21 Nov 2020 18:10:51 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:58:59 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:22:31 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:58:59 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:22:31 |
| User entered 'Clinic (Clinic)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:58:59 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User entered 'SICKD1' | System | 20 Nov 2020 17:58:59 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:03:01 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:03:04 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:03:36 |
| User entered '09:19' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User entered '16 Nov 2020 09:19' | System | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:08 |
| User entered '71' in | Shelby Pickle (b) (4) | 20 Nov 2020 17:59:48 |
| DataPoint set to visible. | (b) (4) System | 20 Nov 2020 17:58:59 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (xxx.x)

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:27 |
| User entered missing code ND - Not Done. | Shelby Pickle (b) (4) | 20 Nov 2020 17:59:48 |
| DataPoint set to visible. | (b) (4) System | 20 Nov 2020 17:58:59 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:29 |
| User entered '98.2' F | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:30 |
| User entered 'Other (Other)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:32 |
| User entered 'Temporal' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:36 |
| User entered '76' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User entered 'bpm' | System | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:38 |
| User entered '14' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User entered 'breaths/min' | System | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:40 |
| User entered '107' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User entered 'mmHg' | System | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:41 |
| User closed query 'Per CDM RQ: Response noted. However please indicate if this value is considered "CS" or "NCS". Thank you.' (Site from DM). | | 24 Nov 2020 12:23:19 |
| Query 'Per CDM RQ: Response noted. However please indicate if this value is considered "CS" or "NCS". Thank you.' answered with 'NCS' (Site from DM). | Shelby Pickle (b) (4) (b) (4) | 23 Nov 2020 21:27:08 |
| User opened query 'Per CDM RQ: Response noted. However please indicate if this value is considered "CS" or "NCS". Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 05:00:43 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 23 Nov 2020 04:57:28 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Information provided is correct' (Site from System). | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:00:03 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 20 Nov 2020 17:59:48 |
| User entered '59' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User entered 'mmHg' | System | 20 Nov 2020 17:59:48 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| | | |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| | | |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:53 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:00:14 |

US3142255

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:04:55 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:00:14 |

US3142255

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:04:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:03 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:00:26 |

US3142255

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:16:39 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:03 |
| User entered '16 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 18:00:26 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:56:35 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:39:18 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:56:35 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '17 Dec 2020' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:39:18 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:56:35 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Clinic (Clinic)' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:39:18 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| User entered 'SICKD28' | System | 03 Feb 2021 00:39:18 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '17 Dec 2020' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '09:00' | (b) (4) | |
| | Shelby Pickle (b) (4) | 03 Feb 2021 00:40:03 |
| | (b) (4) | |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| User entered '17 Dec 2020 09:00' | System | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Height (xxx.x)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:40:03 |
| DataPoint set to visible. | (b) (4) System | 03 Feb 2021 00:39:18 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (xxx.x)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Shelby Pickle (b) (4) | 03 Feb 2021 00:40:03 |
| DataPoint set to visible. | (b) (4) System | 03 Feb 2021 00:39:18 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '98.0' F | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Other (Other)' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Temporal' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Pulse (xxx)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User closed query 'Per CDM: Response noted however please indicate if out of range Pulse is CS or NCS.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 10:24:02 |
| Query 'Per CDM: Response noted however please indicate if out of range Pulse is CS or NCS.' answered with 'ncs' (Site from DM). | Jill York (b) (4) | 22 Feb 2021 19:39:18 |
| User closed 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). | (b) (4), (b) (6) | 11 Feb 2021 18:03:15 |
| User opened query 'Per CDM: Response noted however please indicate if out of range Pulse is CS or NCS.' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 18:03:10 |
| 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 with 'Information provided is accurate' (Site from System). | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:16 |
| 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 | 03 Feb 2021 00:40:03 |
| User entered '43' | Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| User entered 'bpm' | System | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '14' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| User entered 'breaths/min' | System | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '132' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| User entered 'mmHg' | System | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '70' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:03 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| User entered 'mmHg' | System | 03 Feb 2021 00:40:03 |

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| | | |

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:27

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| | | |

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:57 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:23 |

US3142255

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:57:57 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '17 Dec 2020' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:40:23 |

US3142255

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:04:27

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:59:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:41:30 |

US3142255

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:04:27

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:23:24 |
| DataPoint Verified. | | 21 Apr 2021 20:59:29 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '17 Dec 2020' | (b) (4) Shelby Pickle (b) (4) (b) (4) | 03 Feb 2021 00:41:30 |

US3142255

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:40 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:22 |

US3142255

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:40 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:22 |

US3142255

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:40 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:22 |

US3142255

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:40 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'UNBLND_DECIDE' | System | 01 Mar 2021 23:26:22 |

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered '0' | (b) (4) Jami Wagner (b) (4) | 02 Apr 2021 17:07:36 |
| Amendment Manager inserted this DataPoint. | (b) (4) System | 06 Mar 2021 14:00:50 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| | (b) (4) | |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Jami Wagner (b) (4) | 02 Apr 2021 17:07:36 |
| | (b) (4) | |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 14:00:50 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

Date of unblinding (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| User signature succeeded. | Ripley Hollister (b) (4) | 03 May 2021 15:03:43 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| User closed query 'Per Sponsor: IRT unbinding to be updated.' (Site from DM). | | 01 May 2021 09:02:28 |
| User closed query "'As per previous query, date of unblinding MUST be the date of IRT transaction, not when subject visit happened. Please enter date per iRT (24Feb21)". 2 queries answered wrong. (Site from DM). | | 01 May 2021 09:02:24 |
| User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System). | | 01 May 2021 09:02:22 |
| User entered '24 Feb 2021' reason for change: Data Entry Error | Jill York (b) (4) | 30 Apr 2021 18:16:26 |
| Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'done' (Site from System). | Jill York (b) (4) | 29 Apr 2021 23:31:38 |
| Query "'As per previous query, date of unblinding MUST be the date of IRT transaction, not when subject visit happened. Please enter date per iRT (24Feb21)". 2 queries answered wrong. ' answered with 'done' (Site from DM). | Jill York (b) (4) | 29 Apr 2021 23:31:20 |
| User entered '24 Feb 2020' reason for change: Data Entry Error | Jill York (b) (4) | 29 Apr 2021 23:31:03 |
| Query 'Per Sponsor: IRT unbinding to be updated.' answered with 'done' (Site from DM). | Jill York (b) (4) | 29 Apr 2021 23:30:09 |
| User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System). | System | 29 Apr 2021 23:29:51 |
| Signature has been broken. | Jill York (b) (4) | 29 Apr 2021 23:29:51 |
| User entered '24 Feb 2021' reason for change: Data Entry Error | Jill York (b) (4) | 29 Apr 2021 23:29:51 |

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

Date of unblinding (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User opened query "'As per previous query, date of unblinding MUST be the date of IRT transaction, not when subject visit happened. Please enter date per iRT (24Feb21)". 2 queries answered wrong. ' (Site from DM). | (b) (4), (b) (6) | 29 Apr 2021 13:17:49 |
| User opened query 'Per Sponsor: IRT unbinding to be updated.' (Site from DM). | | 29 Apr 2021 08:33:15 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User closed query 'PER CDMRQ: Response noted, however IRT Unblinding date and EDC Unblinding date should be reviewed and reconciled. Kindly review and confirm date that subject was unblinded.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 16:26:03 |
| Query 'PER CDMRQ: Response noted, however IRT Unblinding date and EDC Unblinding date should be reviewed and reconciled. Kindly review and confirm date that subject was unblinded.' answered with '01MAR2021 unblinding date is correct' (Site from DM). | Jill York (b) (4) | 21 Apr 2021 23:25:55 |
| User opened query 'PER CDMRQ: Response noted, however IRT Unblinding date and EDC Unblinding date should be reviewed and reconciled. Kindly review and confirm date that subject was unblinded.' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 16:16:36 |
| User closed query 'Per IRT, subject was unblinded on 24FEB2021. Please review and reconcile.' (Site from DM). | | 15 Apr 2021 16:16:36 |
| Query 'Per IRT, subject was unblinded on 24FEB2021. Please review and reconcile.' answered with 'Per site lab requisition forms Subject has been available for labs for the following days: 26Aug2020, 23Sep2020, 21Oct2020, 16Nov2020, 17Dec2020, and 01Mar2021. please verify number and dates to resubmit.' (Site from DM). | Lisa Jackson (b) (4) (b) (4) | 08 Apr 2021 21:32:55 |
| User opened query 'Per IRT, subject was unblinded on 24FEB2021. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 16:59:03 |

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EAB) (1725)

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered '1 Mar 2021' | (b) (4), (b) (6) | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User closed query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 15 Apr 2021 20:27:44 |
| Query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'Subject has been a Placebo since the start of study' (Site from DM). | Lisa Jackson (b) (4) (b) (4) | 08 Apr 2021 21:36:52 |
| User entered 'Placebo (Placebo)' reason for change: Data Entry Error | Lisa Jackson (b) (4) (b) (4) | 08 Apr 2021 21:33:59 |
| User opened query 'Sponsor Review: Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 16:40:47 |
| User entered 'mRNA-1273 (mRNA-1273)' | | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered '1' | System | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:27

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:41:18 |
| Data hard unlocked. | | 03 May 2021 21:05:10 |
| Data hard locked. | | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:30 |
| Data hard locked. | | 01 May 2021 19:22:59 |
| Data hard unlocked. | | 29 Apr 2021 08:32:01 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'I' | System | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

[Height](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

[Weight](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 05 Apr 2021 21:42:00 |
| DataPoint set to visible. | System | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

[Height](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

[Weight](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 05 Apr 2021 21:42:00 |
| DataPoint set to visible. | System | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:42:00 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '01 Mar 2021' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '14:53' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:42:00 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered '01 Mar 2021 14:53' | System | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '98.6' F | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:42:00 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Other (Other)' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Temporal' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:42:00 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '74' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:42:00 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'bpm' | System | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '12' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'breaths/min' | System | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '105' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:42:00 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'mmHg' | System | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '70' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'mmHg' | System | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

[Height](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

US3142255

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

[Weight](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:42:00 |

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:27

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered empty. | System | 05 Apr 2021 21:42:00 |
| DataPoint set to visible. | System | 01 Mar 2021 23:26:55 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:43:25 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:25 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '01 Mar 2021' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:43:25 |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '15:44' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:25 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered '01 Mar 2021 15:44' | System | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '98.9' F | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:25 |
| | (b) (4) | |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Other (Other)' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Temporal' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:25 |
| | (b) (4) | |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '62' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:25 |
| | (b) (4) | |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'bpm' | System | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|------------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered missing code ND - Not Done. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'breaths/min' | System | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '116' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'mmHg' | System | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '66' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:25 |
| | (b) (4) | |

US3142255

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:25 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'mmHg' | System | 05 Apr 2021 21:43:25 |

US3142255

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:56 |

US3142255

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '01 Mar 2021' | Lisa Jackson (b) (4) | 05 Apr 2021 21:43:56 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:44:36 |
| | (b) (4) | |

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:44:36 |
| | (b) (4) | |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered empty. | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:44:36 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'mRNA-1273' | System | 05 Apr 2021 21:44:36 |
| DataPoint set to visible. | System | 01 Mar 2021 23:26:55 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '01 Mar 2021' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:44:36 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '15:14' | (b) (4) | |
| | Lisa Jackson (b) (4) | 05 Apr 2021 21:44:36 |
| | (b) (4) | |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered '01 Mar 2021 15:14' | System | 05 Apr 2021 21:44:36 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 05 Apr 2021 21:44:36 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'ONCE' | System | 05 Apr 2021 21:44:36 |

US3142255

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:15 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'INTRAMUSCULAR' | System | 05 Apr 2021 21:44:36 |

US3142255

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:08 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:27:21 |

US3142255

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:08 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:27:21 |

US3142255

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:08 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '14:53' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:27:21 |

US3142255

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:27

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:08 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered '1 Mar 2021 14:53' | System | 01 Mar 2021 23:27:21 |

US3142255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:27

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:04 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:27:41 |

US3142255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:27

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:04 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 01MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 12:24:43 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 01MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you. ' answered with 'accession and tracking details cannot be provided ' (Site from DM). | Jill York (b) (4) | 07 Apr 2021 17:51:52 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 01MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide both Accession number and the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 08 Mar 2021 11:14:10 |
| User entered '1 Mar 2021' | | 01 Mar 2021 23:27:41 |

US3142255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:27

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:04 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '15:04' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:27:41 |

US3142255

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:27

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:04 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered '1 Mar 2021 15:04' | System | 01 Mar 2021 23:27:41 |

US3142255

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

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:49 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 23:27:46 |

US3142255

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

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 02:28:46 |
| Data hard unlocked. | | 02 May 2021 06:04:49 |
| Data hard locked. | | 28 Apr 2021 03:51:51 |
| User entered 'l' | System | 01 Mar 2021 23:27:46 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 16 Mar 2021 17:29:39 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered '11 Mar 2021' | Jami Wagner (b) (4) | 16 Mar 2021 17:29:39 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 16 Mar 2021 17:29:39 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:27

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered empty. | (b) (4) Jami Wagner (b) (4) (b) (4) | 16 Mar 2021 17:29:39 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:19:35 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 16 Mar 2021 17:29:45 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User entered 'I' | System | 16 Mar 2021 17:29:45 |

US3142255

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:36:14 |
| User entered '1' | System | 16 Mar 2021 17:29:45 |
| DataPoint set to visible. | System | 16 Mar 2021 17:29:45 |

US3142255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:54:51 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '07 Apr 2021' | Lisa Jackson (b) (4) | 07 Apr 2021 22:54:51 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:54:51 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:27

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'OLD29' | System | 07 Apr 2021 22:54:51 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Lisa Jackson (b) (4) (b) (4) | 07 Apr 2021 22:56:54 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'No (N)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 22:56:54 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 22:56:54 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 22:56:54 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 22:56:54 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:56:54 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:27

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 22:56:54 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Lisa Jackson (b) (4) (b) (4) | 07 Apr 2021 22:57:20 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered 'No (N)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '07 Apr 2021' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '17:20' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 17:20' | System | 07 Apr 2021 23:21:06 |
| User entered empty. | System | 07 Apr 2021 22:57:20 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '97.7' F reason for change: Data Entry | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| Error | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Other (Other)' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[If Other, specify](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'TEMPORAL' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '62' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'bpm' | System | 07 Apr 2021 23:21:06 |
| User entered empty. | System | 07 Apr 2021 22:57:20 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 07 Apr 2021 23:21:06 |
| User entered empty. | System | 07 Apr 2021 22:57:20 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '126' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 07 Apr 2021 23:21:06 |
| User entered empty. | System | 07 Apr 2021 22:57:20 |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '72' reason for change: Data Entry Error | Lisa Jackson (b) (4) | 07 Apr 2021 23:21:06 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:20 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:27

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 07 Apr 2021 23:21:06 |
| User entered empty. | System | 07 Apr 2021 22:57:20 |

US3142255

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:49 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:27

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '07 Apr 2021' | Lisa Jackson (b) (4) | 07 Apr 2021 22:57:49 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:30 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:30 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:30 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'mRNA-1273' | System | 07 Apr 2021 22:58:30 |
| DataPoint set to visible. | System | 16 Mar 2021 17:29:45 |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '07 Apr 2021' | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:30 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered '16:50' | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:30 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 16:50' | System | 07 Apr 2021 22:58:30 |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Left Arm (LEFT ARM)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:30 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 07 Apr 2021 22:58:30 |

US3142255

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:27

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 07 Apr 2021 22:58:30 |

US3142255

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Lisa Jackson (b) (4) | 07 Apr 2021 22:58:38 |
| | (b) (4) | |

US3142255

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:27

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 07 Apr 2021 22:58:38 |

US3142255

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:04:27

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:39:50 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:23:35 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:15:18 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 19:58:12 |
| User entered 'USA-US064-2020-mRNA-1273-P301000005' | System | 23 Nov 2020 19:57:30 |
| User entered 'New' | (b) (4), (b) (6) | 23 Nov 2020 19:57:30 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| 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) | 20 Nov 2020 17:18:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Nov 2020 17:18:03 |
| Data point term sent to Coder | System | 20 Nov 2020 17:17:47 |
| User entered 'COVID-19' | Shelby Pickle (b) (4) | 20 Nov 2020 17:16:59 |
| | (b) (4) | |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User closed query 'Please reconcile as per protocol an illness visit = MAAE' (Site from CRA). | | 24 Nov 2020 03:17:05 |
| Query 'Please reconcile as per protocol an illness visit = MAAE' answered with 'Updated. Only protocol procedures completed.' (Site from CRA). | Shelby Pickle (b) (4) | 23 Nov 2020 21:29:07 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Shelby Pickle (b) (4) | 23 Nov 2020 21:28:45 |
| User opened query 'Please reconcile as per protocol an illness visit = MAAE' (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 22:40:31 |
| User entered 'No (N)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:16:59 |
| | (b) (4) | |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '13 Nov 2020' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 20:44:44 |
| DataPoint Un-verified. | Jill York (b) (4) | 19 Apr 2021 23:01:58 |
| User entered 'No (N)' reason for change: Data Entry Error | Jill York (b) (4) | 19 Apr 2021 23:01:58 |
| User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 19 Apr 2021 08:28:08 |
| Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with '01Dec2020 Telemedicine call is the completion of this visit. 01DEC2020, 01DEC2020, and 17DEC2020 visit.' (Site from DM). | Lisa Jackson (b) (4) (b) (4) | 14 Apr 2021 21:17:18 |
| User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 04:03:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'Yes (Y)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 20:44:50 |
| DataPoint Un-verified. | Jill York (b) (4) | 19 Apr 2021 23:01:58 |
| User entered '17 Dec 2020' reason for change: Data Entry Error | Jill York (b) (4) | 19 Apr 2021 23:01:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety). | (b) (4), (b) (6) | 29 Apr 2021 15:04:21 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | | 07 Dec 2020 15:50:46 |
| User entered empty. | System | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'No (N)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'Not Related (NOT RELATED)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'Not Related (NOT RELATED)' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

Action taken with investigational product

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 21 Apr 2021 20:45:25 |
| User closed query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | | 03 Feb 2021 22:24:57 |
| Query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'corrected ' (Site from Safety). | Meghan York (b) (4) | 28 Jan 2021 18:03:48 |
| DataPoint Un-verified. | (b) (4) | |
| | Meghan York (b) (4) | 28 Jan 2021 18:03:38 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 28 Jan 2021 18:03:38 |
| User opened query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 07 Dec 2020 15:50:07 |
| DataPoint Verified. | | |
| | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered 'None (NONE)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:16:59 |
| | (b) (4) | |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

None

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 22:11:01 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 24 Nov 2020 21:46:42 |
| DataPoint Un-verified. | Jill York (b) (4) | 24 Nov 2020 21:46:42 |
| User entered '1' reason for change: Data Entry Error | Jill York (b) (4) | 24 Nov 2020 21:46:42 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 24 Nov 2020 21:46:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) | 20 Nov 2020 17:16:59 |
| | (b) (4) | |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User closed query 'Please reconcile as there are no medications on Con Med log for COVID-19 or any associated symptoms . If con meds were taken for COVID 19 infection, please consider capturing on Con Med log else consider unticking box.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 22:11:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 22:11:04 |
| Query 'Please reconcile as there are no medications on Con Med log for COVID-19 or any associated symptoms . If con meds were taken for COVID 19 infection, please consider capturing on Con Med log else consider unticking box.' answered with 'no conmeds to report yet' (Site from CRA). | Jill York (b) (4) | 24 Nov 2020 21:46:56 |
| DataPoint Un-verified. | Jill York (b) (4) | 24 Nov 2020 21:46:30 |
| User entered '0' reason for change: Data Entry Error | Jill York (b) (4) | 24 Nov 2020 21:46:30 |
| User opened query 'Please reconcile as there are no medications on Con Med log for COVID-19 or any associated symptoms . If con meds were taken for COVID 19 infection, please consider capturing on Con Med log else consider unticking box.' (Site from CRA). | (b) (4), (b) (6) | 24 Nov 2020 16:29:21 |
| Query 'Please reconcile as there are no medications on Con Med log for COVID-19 or any associated symptoms' canceled (Site from CRA). | (b) (4), (b) (6) | 24 Nov 2020 16:27:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User opened query 'Please reconcile as there are no medications on Con Med log for COVID-19 or any associated symptoms' (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 22:41:18 |
| User entered '1' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered '0' | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Outcome](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 21 Apr 2021 20:44:59 |
| 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). | | 20 Apr 2021 19:33:39 |
| 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 'resolution date added' (Site from Safety). | Jill York (b) (4) | 19 Apr 2021 23:02:20 |
| DataPoint Un-verified. | Jill York (b) (4) | 19 Apr 2021 23:01:58 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Jill York (b) (4) | 19 Apr 2021 23:01:58 |
| Data Entry Error | | |
| 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) | 07 Dec 2020 15:51:16 |
| DataPoint Verified. | | 24 Nov 2020 16:05:53 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Shelby Pickle (b) (4) | 20 Nov 2020 17:16:59 |
| | (b) (4) | |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:05:53 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Narrative](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| 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' canceled (Site from Safety). 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) (4), (b) (6) | 17 Apr 2021 17:05:06 |
| DataPoint Verified. | | 07 Dec 2020 15:51:59 |
| User entered empty. | Shelby Pickle (b) (4) (b) (4) | 24 Nov 2020 16:05:53 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 20 Nov 2020 17:16:59 |

US3142255

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Nov 2020 21:28:45 |
| User entered '0' | System | 20 Nov 2020 17:16:59 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:04:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:39:50 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:10:19 |
| DataPoint Un-verified. | | 24 Nov 2020 15:58:33 |
| DataPoint Verified. | | 24 Nov 2020 15:58:24 |
| User entered 'Yes (Y)' | Meghan York (b) (4) | 13 Nov 2020 16:43:35 |
| | (b) (4) | |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 25 Jan 2021 18:54:56 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 25 Jan 2021 18:54:56 |
| Data point term sent to Coder | System | 25 Jan 2021 18:54:15 |
| Coding entries removed. | Meghan York (b) (4) (b) (4) | 25 Jan 2021 18:53:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 13 Nov 2020 17:00:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 13 Nov 2020 17:00:48 |
| Data point term sent to Coder | System | 13 Nov 2020 16:44:41 |
| User entered 'Advil' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'No (N)' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User closed query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this timeframe. If the PAIN AFTER SECOND VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AFTER SECOND VACCINATION did not meet the AE reporting criteria.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 10:14:57 |
| Query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this timeframe. If the PAIN AFTER SECOND VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AFTER SECOND VACCINATION did not meet the AE reporting criteria.' answered with 'not considered an AE' (Site from DM). | Jill York (b) (4) | 07 Apr 2021 17:54:34 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE matching this Con Med indication during this timeframe. If the PAIN AFTER SECOND VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AFTER SECOND VACCINATION did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 08 Mar 2021 03:52:03 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location and/or type of PAIN (eg, injection site pain, muscle pain, joint pain, etc). Review and update indication as appropriate.' (Site from DM). | | 29 Jan 2021 04:24:48 |
| Query 'Per DM CLR: Please update the indication to reflect the location and/or type of PAIN (eg, injection site pain, muscle pain, joint pain, etc). Review and update indication as appropriate.' answered with 'location and type of pain unknown' (Site from DM). DataPoint Un-verified. | Meghan York (b) (4) (b) (4) | 25 Jan 2021 18:53:55 |
| | Meghan York (b) (4) (b) (4) | 25 Jan 2021 18:53:46 |
| User entered 'PAIN AFTER SECOND VACCINATION (location and type of pain unknown)' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 25 Jan 2021 18:53:46 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and/or type of PAIN (eg, injection site pain, muscle pain, joint pain, etc). Review and update indication as appropriate.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 09:37:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'pain after second vaccination' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered '400' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'mg (mg)' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered empty. | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'once (ONCE)' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered empty. | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'Oral (ORAL)' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered empty. | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered '23 Sep 2020' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered '0' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'No (N)' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered '23 Sep 2020' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 16:10:13 |
| User entered 'Yes (Y)' | Meghan York (b) (4) (b) (4) | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:27

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:44:30 |

US3142255

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:04:27

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| | (b) (4) | |
| User entered 'No (N)' | Jami Wagner (b) (4) | 18 Mar 2021 21:15:41 |
| | (b) (4) | |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[SAEID](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'USA-US064-2020-MRNA-1273-P301000005' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Ripley' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Hollister' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '4190 East Woodmen Road Suite 210' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Colorado Springs' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| Signature has been broken. | System | 20 Apr 2021 19:36:22 |
| User entered empty. | System | 20 Apr 2021 19:36:22 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'COLORADO' | Lisa Jackson (b) (4) | 14 Apr 2021 21:32:47 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '80920' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| User entered 'US' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 20 Apr 2021 19:36:22 |
| User entered '2' | System | 03 Feb 2021 22:25:18 |
| User entered '1' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[SAEID](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'USA-US064-2020-MRNA-1273-P301000005' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Ripley' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Hollister' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '4190 East Woodmen Road Suite 210' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Nov 2020 19:58:25 |
| User entered 'Colorado Springs' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| Signature has been broken. | System | 20 Apr 2021 19:36:22 |
| User entered empty. | System | 20 Apr 2021 19:36:22 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'COLORADO' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 14 Apr 2021 21:32:47 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '80920' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| User entered 'US' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 20 Apr 2021 19:36:22 |
| User entered '2' | System | 03 Feb 2021 22:25:18 |
| User entered '1' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:04:27

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| User entered '23/Nov/2020 14:58' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:04:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| User entered 'I' | | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[SAEID](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'USA-US064-2020-MRNA-1273-P301000005' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Ripley' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Hollister' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '4190 East Woodmen Road Suite 210' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Colorado Springs' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| Signature has been broken. | System | 20 Apr 2021 19:36:22 |
| User entered empty. | System | 20 Apr 2021 19:36:22 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'COLORADO' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 14 Apr 2021 21:32:47 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '80920' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| User entered 'US' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 20 Apr 2021 19:36:22 |
| User entered '2' | System | 03 Feb 2021 22:25:18 |
| User entered '1' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:04:27

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered '03/Feb/2021 17:25' | (b) (4) System | 03 Feb 2021 22:25:18 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:04:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| Reviewed for Safety. | | 20 Apr 2021 19:36:26 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 22:25:18 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[SAEID](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'USA-US064-2020-MRNA-1273-P301000005' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'No (N)' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Ripley' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Hollister' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '4190 East Woodmen Road Suite 210' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered 'Colorado Springs' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| Signature has been broken. | System | 20 Apr 2021 19:36:22 |
| User entered empty. | System | 20 Apr 2021 19:36:22 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| User entered 'COLORADO' | (b) (4) Lisa Jackson (b) (4) (b) (4) | 14 Apr 2021 21:32:47 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| Reviewed for Safety. | | 23 Nov 2020 19:58:25 |
| User entered '80920' | System | 23 Nov 2020 19:57:30 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:32:44 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 00:25:39 |
| User entered 'US' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:04:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 20 Apr 2021 19:36:22 |
| User entered '2' | System | 03 Feb 2021 22:25:18 |
| User entered '1' | System | 23 Nov 2020 19:58:41 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:04:27

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| User entered '20/Apr/2021 15:36' | (b) (4) System | 20 Apr 2021 19:36:22 |

US3142255

Folder: SAE USA-US064-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:04:27

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 18:30:49 |
| User signature succeeded. | Ripley Hollister (b) (4) | 26 Apr 2021 02:45:32 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 19:36:26 |
| User entered 'I' | | 20 Apr 2021 19:36:22 |