

US3342046 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:22:23

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US3342046

**Form: Participant Creation**

**Data signed:** (b) (4) 12 Mar 2021 23:15:08

**Generated On:** 11 Aug 2021 22:22:23

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[Participant ID](#)

US3342046

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

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US3342046

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 13 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1979                                                                                                                                                               |
| Age                                       | 41                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 41                                                                                                                                                                         |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 13 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 checked="" type="radio"/> |
|                                                 | Amendment 3 <input type="radio"/>            |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Mar 2021 23:15:10

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Mar 2021 23:15:10

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | SEASONAL ALLERGIES                                               |
| Start date (dd MMM yyyy)                                | UN UNK 1980                                                      |
| Start date completely unknown                           | False                                                            |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>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 1980                                                         |
| Start Year (derived)                                    | 1980                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | CERVICAL DISK HERNIATION                                         |
| Start date (dd MMM yyyy)                                | UN UNK 2013                                                      |
| Start date completely unknown                           | False                                                            |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |                                                                  |
| Stop date completely unknown                            | False                                                            |
| Start Month and Year (derived)                          | JAN 2013                                                         |
| Start Year (derived)                                    | 2013                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 13 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 08:45 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 13 AUG 2020 08:45                    |
| Height ( <i>xxx.x</i> )                   | 183.0 cm                             |
| Weight ( <i>xxx.x</i> )                   | 88.9 kg                              |
| BMI ( <i>xxx.x</i> )                      | 26.54603 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|                                           | Axillary <input type="radio"/>       |
|                                           | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

### 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

ENGINEER INSPECTOR, WORKS  
IN OFFICE AND TRAVELS TO  
~20 HOMES DAILY FOR WORK

### Location and Living Circumstances Risk (check all that apply)

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Mar 2021 23:15:10

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 13 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) 29 Mar 2021 15:02:48

Generated On: 11 Aug 2021 22:22:23

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103758

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/m<sup>2</sup>) Yes ☐ No ☒

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|        |               |
|--------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height                              | ND - Not Done                                                                                          |
| Weight                              | ND - Not Done                                                                                          |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 13 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 08:45 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 13 AUG 2020 08:45                                                                                      |
| Temperature (xxx.x)                 | 97.8 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 78 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 121 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 86 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| Height                              | ND - Not Done                                                                                          |
| Weight                              | ND - Not Done                                                                                          |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 13 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 10:15 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 13 AUG 2020 10:15                                                                                      |
| Temperature (xxx.x)                 | 98.0 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 66 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 122 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 83 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

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) 13 AUG 2020

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

Treatment Date and Time (derived) 13 AUG 2020 09:45

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 13 AUG 2020                          |
| Collection time (00:00-23:59)      | 09:17 (24 HR)                        |
| Collection date and time (derived) | 13 AUG 2020 09:17                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 13 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:20                           | 13 AUG 2020 09:20                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 10:18

PC Open Date & Time

13 AUG 2020 10:05

PC Close Date & Time

13 AUG 2020 12:35



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 13 AUG 2020 19:27 |
| PC Open Date & Time  | 13 AUG 2020 13:30 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 18:09

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 18:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 15:54

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 16:49

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 16:53

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 19:16

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 10:19

PC Open Date & Time

13 AUG 2020 10:05

PC Close Date & Time

13 AUG 2020 12:35



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**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

13 AUG 2020 19:27

PC Open Date & Time

13 AUG 2020 13:30

PC Close Date & Time

14 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 18:06

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**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

15 AUG 2020 18:38

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

| TIMEPOINT                                                                                  | DAY 4                                 |
|--------------------------------------------------------------------------------------------|---------------------------------------|
| Please record - <b>PAIN AT INJECTION SITE.</b>                                             | None <input checked="" type="radio"/> |
| Please select one response below                                                           |                                       |
| 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 <b>REDNESS AT INJECTION SITE?</b>                                             | Yes <input type="radio"/>             |
|                                                                                            | No <input checked="" type="radio"/>   |
| Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>                                   | Yes <input type="radio"/>             |
|                                                                                            | No <input checked="" type="radio"/>   |
| Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>                              | None <input checked="" type="radio"/> |
| Please select one response below                                                           |                                       |
| 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                                                                              | 16 AUG 2020 15:54                     |
| PC Open Date & Time                                                                        | 16 AUG 2020 12:00                     |
| PC Close Date & Time                                                                       | 17 AUG 2020 11:59                     |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**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

17 AUG 2020 16:49

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:53

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

| TIMEPOINT                                                                                  | DAY 7                                 |
|--------------------------------------------------------------------------------------------|---------------------------------------|
| Please record - <b>PAIN AT INJECTION SITE.</b>                                             | None <input checked="" type="radio"/> |
| Please select one response below                                                           |                                       |
| 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 <b>REDNESS AT INJECTION SITE?</b>                                             | Yes <input type="radio"/>             |
|                                                                                            | No <input checked="" type="radio"/>   |
| Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>                                   | Yes <input type="radio"/>             |
|                                                                                            | No <input checked="" type="radio"/>   |
| Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>                              | None <input checked="" type="radio"/> |
| Please select one response below                                                           |                                       |
| 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                                                                              | 19 AUG 2020 19:16                     |
| PC Open Date & Time                                                                        | 19 AUG 2020 12:00                     |
| PC Close Date & Time                                                                       | 20 AUG 2020 11:59                     |

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Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**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 ☐



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 13 AUG 2020 10:20 |
| PC Open Date & Time  | 13 AUG 2020 10:05 |
| PC Close Date & Time | 13 AUG 2020 12:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**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 ☐

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 13 AUG 2020 19:27 |
| PC Open Date & Time  | 13 AUG 2020 13:30 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 AUG 2020 18:06 |
| PC Open Date & Time          | 14 AUG 2020 12:00 |
| PC Close Date & Time         | 15 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 15 AUG 2020 18:39 |
| PC Open Date & Time          | 15 AUG 2020 12:00 |
| PC Close Date & Time         | 16 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**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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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 16 AUG 2020 15:55 |
| PC Open Date & Time          | 16 AUG 2020 12:00 |
| PC Close Date & Time         | 17 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 AUG 2020 16:49 |
| PC Open Date & Time          | 17 AUG 2020 12:00 |
| PC Close Date & Time         | 18 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2264

EAB) (1725)

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 18 AUG 2020 16:54 |
| PC Open Date & Time          | 18 AUG 2020 12:00 |
| PC Close Date & Time         | 19 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 2264

EAB) (1725)

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 AUG 2020 19:16 |
| PC Open Date & Time          | 19 AUG 2020 12:00 |
| PC Close Date & Time         | 20 AUG 2020 11:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

|                                                                                                 |                                                                  |
|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                | DAY 8                                                            |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                   | 21 AUG 2020 06:41                                                |
| PC Open Date & Time                                                                             | 20 AUG 2020 12:00                                                |
| PC Close Date & Time                                                                            | 21 AUG 2020 11:59                                                |



US3342046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342046

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342046

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342046

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| 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)    | 16 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 09:30 (24 HR)                             |
| Vital Signs Date and Time (derived) | 16 SEP 2020 09:30                         |
| Temperature (xxx.x)                 | 97.4 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 81 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 142 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 93 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |



US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| 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)    | 16 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 10:43 (24 HR)                              |
| Vital Signs Date and Time (derived) | 16 SEP 2020 10:43                          |
| Temperature (xxx.x)                 | 99.4 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |                                            |
| Pulse (xxx)                         | 74 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | 16 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 134 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 92 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

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.*

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 10:11 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 10:11

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

US3342046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

16 SEP 2020 09:55

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 16 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:57                           | 16 SEP 2020 09:57                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:21

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**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

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 10:46

PC Open Date & Time

16 SEP 2020 10:31

PC Close Date & Time

16 SEP 2020 13:01

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**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 96.7 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 16 SEP 2020 18:09 |
| PC Open Date & Time  | 16 SEP 2020 13:56 |
| PC Close Date & Time | 17 SEP 2020 11:59 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 20:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**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

97.9 °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

18 SEP 2020 23:59

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 19:36

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 17:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 18:57

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**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

16 SEP 2020 10:47

PC Open Date & Time

16 SEP 2020 10:31

PC Close Date & Time

16 SEP 2020 13:01

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**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

16 SEP 2020 18:09

PC Open Date & Time

16 SEP 2020 13:56

PC Close Date & Time

17 SEP 2020 11:59



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:34

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**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

18 SEP 2020 23:59

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**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

19 SEP 2020 19:36

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**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

20 SEP 2020 20:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 7

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

22 SEP 2020 18:57

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**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 ☐

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 16 SEP 2020 10:47 |
| PC Open Date & Time  | 16 SEP 2020 10:31 |
| PC Close Date & Time | 16 SEP 2020 13:01 |



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Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**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 ☐

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Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 16 SEP 2020 18:09 |
| PC Open Date & Time  | 16 SEP 2020 13:56 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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 ☒

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EAB) (1725)

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 17 SEP 2020 20:34 |
| PC Open Date & Time          | 17 SEP 2020 12:00 |
| PC Close Date & Time         | 18 SEP 2020 11:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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)

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 SEP 2020 00:00 |
| PC Open Date & Time          | 18 SEP 2020 12:00 |
| PC Close Date & Time         | 19 SEP 2020 11:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 19 SEP 2020 19:36 |
| PC Open Date & Time          | 19 SEP 2020 12:00 |
| PC Close Date & Time         | 20 SEP 2020 11:59 |



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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 SEP 2020 20:55 |
| PC Open Date & Time          | 20 SEP 2020 12:00 |
| PC Close Date & Time         | 21 SEP 2020 11:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 SEP 2020 17:59 |
| PC Open Date & Time          | 21 SEP 2020 12:00 |
| PC Close Date & Time         | 22 SEP 2020 11:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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 ☒

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US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 SEP 2020 18:57 |
| PC Open Date & Time          | 22 SEP 2020 12:00 |
| PC Close Date & Time         | 23 SEP 2020 11:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**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 23 SEP 2020 19:58

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 23 SEP 2020 19:58

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59



US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 SEP 2020 19:58

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 22:44

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 23 SEP 2020 19:58

---

PC Open Date & Time 23 SEP 2020 12:00

---

PC Close Date & Time 24 SEP 2020 11:59

---

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 24 SEP 2020 22:44

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

|                                                                                                 |                                                                  |
|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                | DAY 8                                                            |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                   | 23 SEP 2020 19:58                                                |
| PC Open Date & Time                                                                             | 23 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                            | 24 SEP 2020 11:59                                                |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:22:23

|                                                                                                 |                                                                  |
|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                | DAY 9                                                            |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                   | 24 SEP 2020 22:44                                                |
| PC Open Date & Time                                                                             | 24 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                            | 25 SEP 2020 11:59                                                |

US3342046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342046

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3342046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342046

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 14 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                                  |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 14 OCT 2020                           |
| Time of assessment (00:00-23:59)    | 08:15 (24 HR)                         |
| Vital Signs Date and Time (derived) | 14 OCT 2020 08:15                     |
| Temperature (xxx.x)                 | 98.5 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 65 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 13 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 141 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 100 mmHg                              |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

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.*

US3342046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

08:47 (24 HR)

Collection date and time (derived)

14 OCT 2020 08:47



US3342046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:22

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**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

16 OCT 2020 09:25:48

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 12:03:07

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

| TIMEPOINT                                                                                                                                                                       | DAY 78                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>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"/><br>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"/><br>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"/><br>Yes <input type="radio"/>                                               |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 17:54:54

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

| TIMEPOINT                                                                                                                                                                       | DAY 99                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>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"/><br>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"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq$ 100.4°F/38°C)                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59



US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

| TIMEPOINT                                                                                                                                                                       | DAY 103                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>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"/><br>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 type="radio"/><br>Yes <input checked="" type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                                |
| Fever (Temperature $\geq$ 100.4°F/38°C)                                                                                                                                         | True                                                                                                           |
| Chills                                                                                                                                                                          | True                                                                                                           |
| Cough                                                                                                                                                                           | True                                                                                                           |
| Shortness of breath                                                                                                                                                             | True                                                                                                           |
| Difficulty breathing                                                                                                                                                            | True                                                                                                           |
| Fatigue                                                                                                                                                                         | True                                                                                                           |
| Muscle aches                                                                                                                                                                    | True                                                                                                           |
| Body aches                                                                                                                                                                      | True                                                                                                           |
| Headache                                                                                                                                                                        | True                                                                                                           |
| New loss of taste                                                                                                                                                               | False                                                                                                          |
| New loss of smell                                                                                                                                                               | False                                                                                                          |
| Sore throat                                                                                                                                                                     | True                                                                                                           |
| Congestion                                                                                                                                                                      | True                                                                                                           |
| Runny nose                                                                                                                                                                      | True                                                                                                           |
| Nausea                                                                                                                                                                          | False                                                                                                          |
| Vomiting                                                                                                                                                                        | False                                                                                                          |
| Diarrhea                                                                                                                                                                        | False                                                                                                          |
| Please contact your study clinic immediately. Click below to confirm that you have read this message 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 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"/><br>Yes <input checked="" type="radio"/>                                               |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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     | 24 NOV 2020 18:02:38 |
| Patient Cloud Open Date & Time  | 21 NOV 2020 00:01    |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59    |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

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

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**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

07 DEC 2020 12:00:24

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

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

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**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

22 DEC 2020 18:04:02

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59



US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

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

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

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

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3342046

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:22:23**

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

US3342046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342046

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments



US3342046

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

|                                                  |                                                                                                                                                                                                                                          |
|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Contact                                  | 20 NOV 2020                                                                                                                                                                                                                              |
| Time of Contact                                  | 12:45                                                                                                                                                                                                                                    |
| Date and Time of Contact (derived)               | 20 NOV 2020 12:45                                                                                                                                                                                                                        |
| Type of Contact                                  | <div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>                                                                                                                                                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |             |                                     |
|----------------------|-------------|-------------------------------------|
|                      | 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        | 99 %        |                                     |
| O2 Saturation Units  | %           |                                     |
| Temperature          | 99.4 F      |                                     |
| Chills               | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input checked="" type="checkbox"/> |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Cough                | None        | <input type="checkbox"/>            |
|                      | Mild        | <input checked="" 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 checked="" type="checkbox"/> |
|                      | Severe      | <input type="checkbox"/>            |
|                      | Not Done    | <input type="checkbox"/>            |
| Difficulty Breathing | None        | <input type="checkbox"/>            |
|                      | Mild        | <input type="checkbox"/>            |
|                      | Moderate    | <input checked="" type="checkbox"/> |
|                      | Severe      | <input type="checkbox"/>            |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 ☐

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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"/>            |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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        | 93 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.1 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 type="radio"/>            |
|                      | Moderate    | <input checked="" 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 20 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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 type="radio"/>            |
|                        | Mild     | <input checked="" 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 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"/>            |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 (3)

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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                 | 22 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 95 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.1 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 checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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 type="radio"/>            |
|                        | Mild     | <input checked="" 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 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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Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | 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        | 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 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 checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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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 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 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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Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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                 | 17 NOV 2020   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input type="radio"/>            |
|                      | Mild          | <input checked="" type="radio"/> |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" 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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Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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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Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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

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Form: Symptom Log (6)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" 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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Form: Symptom Log (6)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Form: Symptom Log (7)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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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Form: Symptom Log (7)

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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                 | 19 NOV 2020   |                                     |
| Assessment Not Done  | False         |                                     |
| O2 Saturation        | ND - Not Done |                                     |
| O2 Saturation Units  | %             |                                     |
| Temperature          | ND - Not Done |                                     |
| Chills               | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input checked="" type="checkbox"/> |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Cough                | None          | <input type="checkbox"/>            |
|                      | Mild          | <input checked="" 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 checked="" type="checkbox"/> |
|                      | Severe        | <input type="checkbox"/>            |
|                      | Not Done      | <input type="checkbox"/>            |
| Difficulty Breathing | None          | <input type="checkbox"/>            |
|                      | Mild          | <input type="checkbox"/>            |
|                      | Moderate      | <input checked="" type="checkbox"/> |
|                      | Severe        | <input type="checkbox"/>            |

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Form: Symptom Log (7)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input checked="" 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 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 type="radio"/>            |
|                        | Moderate | <input checked="" 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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Form: Symptom Log (7)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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) 12 Apr 2021 15:26:50

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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                 | 24 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 97 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.0 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 checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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Form: Symptom Log (8)

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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 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 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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Form: Symptom Log (8)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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) 12 Apr 2021 15:26:50

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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                 | 25 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.8 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input 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 (9)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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 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 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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Form: Symptom Log (9)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 (10)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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

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Form: Symptom Log (10)

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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 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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Form: Symptom Log (10)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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) 12 Apr 2021 15:26:50

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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                 | 27 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.1 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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EAB) (1725)

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Form: Symptom Log (11)

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Generated On: 11 Aug 2021 22:22:23

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

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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) 12 Apr 2021 15:26:50

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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                 | 28 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.5 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input 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 (12)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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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Form: Symptom Log (12)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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 ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 12 Apr 2021 15:26:50

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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) 12 Apr 2021 15:26:50

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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                 | 29 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 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 (13)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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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Form: Symptom Log (13)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

Symptom Day

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

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 30 NOV 2020 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 99 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.7 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input 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 20 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |            |                                  |
|----------------------|------------|----------------------------------|
|                      | 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                 | 1 DEC 2020 |                                  |
| Assessment Not Done  | False      |                                  |
| O2 Saturation        | 99 %       |                                  |
| 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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EAB) (1725)

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Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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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Form: Symptom Log (15)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |            |                                  |
|----------------------|------------|----------------------------------|
|                      | 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                 | 2 DEC 2020 |                                  |
| Assessment Not Done  | False      |                                  |
| O2 Saturation        | 99 %       |                                  |
| 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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EAB) (1725)

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Form: Symptom Log (16)

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Generated On: 11 Aug 2021 22:22:23

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | 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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Form: Symptom Log (16)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 20 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |                      |                          |
|----------------------|----------------------|--------------------------|
|                      | 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                 | 3 DEC 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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Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                        |          |                          |
|------------------------|----------|--------------------------|
|                        | 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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Form: Symptom Log (17)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                         |          |                          |
|-------------------------|----------|--------------------------|
| 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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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

Symptom Day

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

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

|                      |            |                                  |
|----------------------|------------|----------------------------------|
|                      | 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                 | 4 DEC 2020 |                                  |
| Assessment Not Done  | False      |                                  |
| O2 Saturation        | 99 %       |                                  |
| O2 Saturation Units  | %          |                                  |
| Temperature          | 98.3 F     |                                  |
| Chills               | None       | <input checked="" type="radio"/> |
|                      | Mild       | <input type="radio"/>            |
|                      | Moderate   | <input type="radio"/>            |
|                      | Severe     | <input type="radio"/>            |
|                      | Not Done   | <input type="radio"/>            |
| Cough                | None       | <input 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"/>            |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Apr 2021 15:26:50

Generated On: 11 Aug 2021 22:22:23

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 ☐

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

|                                                                               |                                                                                                                                                              |
|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Visit                                                                 | 20 NOV 2020                                                                                                                                                  |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR?                           | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                             |
| Date of Test                                                                  | 20 NOV 2020                                                                                                                                                  |
| Type of Test Performed                                                        | Nasopharyngeal Swab <input checked="" type="radio"/><br>Nasal Swab <input type="radio"/><br>Saliva Test <input type="radio"/><br>Other <input type="radio"/> |
| Other, specify                                                                |                                                                                                                                                              |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                             |
| If yes, provide lab information below                                         |                                                                                                                                                              |
| Lab/ Institution Test Performed                                               |                                                                                                                                                              |
| CLIA Certified?                                                               | Yes <input type="radio"/><br>No <input type="radio"/>                                                                                                        |
| COVID-19 Positive (CSA Programming Field Only)                                | 1                                                                                                                                                            |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 21 NOV 2020  
End Date 21 NOV 2020  
Oxygen Saturation 93 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_  
End Date \_\_\_\_\_  
PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

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

Start Date \_\_\_\_\_

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  | Yes                   | 22 NOV 2020        |
| Day 5  | Yes                   | 24 NOV 2020        |
| Day 7  | Yes                   | 26 NOV 2020        |
| Day 9  | Yes                   | 28 NOV 2020        |
| Day 14 | Yes                   | 03 DEC 2020        |
| Day 21 | Yes                   | 10 DEC 2020        |
| Day 28 | Yes                   | 17 DEC 2020        |



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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 20 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                                  |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 20 NOV 2020                           |
| Time of assessment (00:00-23:59)    | 12:58 (24 HR)                         |
| Vital Signs Date and Time (derived) | 20 NOV 2020 12:58                     |
| Height (xxx.x)                      | ND - Not Done                         |
| Weight (xxx.x)                      | ND - Not Done                         |
| Temperature (xxx.x)                 | 99.4 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 86 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 14 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 144 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 102 mmHg                              |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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

US3342046

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 NOV 2020

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| 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)    | 13:55 (24 HR)                         |
| Vital Signs Date and Time (derived) | 17 DEC 2020 13:55                     |
| Height (xxx.x)                      | ND - Not Done                         |
| Weight (xxx.x)                      | ND - Not Done                         |
| Temperature (xxx.x)                 | 98.2 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 71 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 12 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 160 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 103 mmHg                              |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

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.*

US3342046

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 22 Mar 2021 13:27:05

Generated On: 11 Aug 2021 22:22:23

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 DEC 2020



US3342046

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

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3342046

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

Form: Unblinding

Generated On: 11 Aug 2021 22:22:23

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

US3342046

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

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

|                                        |       |
|----------------------------------------|-------|
| Collection date ( <i>dd MMM yyyy</i> ) | _____ |
| Collection time ( <i>00:00-23:59</i> ) | _____ |
| Collection date and time (derived)     | _____ |

US3342046

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:22:23

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00 - 23:59*)

Collection Date and Time (derived)

US3342046

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:15:09

Generated On: 11 Aug 2021 22:22:23

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US203-2020-MRNA-1273-P30<br>1000008                                                                                                                          |
| Adverse event                                                  | SYMPTOMATIC COVID-19<br>INFECTION                                                                                                                                |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 17 NOV 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 26 DEC 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>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"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 237 of 2264                                                                                                                                                      |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

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

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

PT REPORTS SX OF COUGH, FATIGUE, & SNEEZING ONSET 17NOV2020 & SX OF HA, BODY ACHES, CHILLS, & FV (100.5 F & 101 F) ONSET 19NOV2020. ALL SX ONGOING AT ILLNESS VISIT (20NOV2020 @1300). PT REPORTS HAVING TAKEN ACETAMINOPHEN 975MG PO PRN FOR BODY ACHES ON 19NOV2020, CURRENTLY ONGOING MEDICATION AS PT PLANS TO TAKE ADDITIONAL DOSES THROUGHOUT ILLNESS. (PT INSTRUCTED TO COME IN FOR ILLNESS VISIT. ILLNESS VISIT COMPLETED.) DAO 20NOV2020

UPDATE: PT CAME IN FOR DAY 28CONV F/U APPT. PT ONLY SX @ VISIT MILD FATIGUE & MUSCLE ACHES. (SUBJECT HAD PREVIOUSLY REPORTAD @ MULTIPLE DAILY TELE-HEALTH VISITS AS HAVING NO SYMPTOMS (PER AE SOURCE). PT HAD ELEVATED BP@ DAY 28 CONVALESCENT VISIT F/U (160/103). HR 71 BPM. PT HAS NO DIAGNOSIS OF HTN AND NO RX. PT IS F/U W/ PCP TO MONITOR ELEVATED BP DUE TO POSITIVE COVID RESULT (PER ELEVATED BP AE SOURCE) SUBJECT ALSO REPORTS KNOWN EXPOSURE TO SOMEONE W/ COVID-19 ON 24NOV2020 (PER COVID-19 AE SOURCE).

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

---

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

AEID

Adverse event

ELEVATED BLOOD PRESSURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

17 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☐  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☒

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐  
Not Recovered/Not Resolved ☒  
Recovered/Resolved ☐  
Recovered/Resolved with ☐  
Sequelae ☐  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative PT HAD ELEVATED BLOOD  
PRESSURE @ DAY 28  
CONVALESCENT VISIT F/UI  
(160/103). HR 71 BPM. PT NO HX  
OF HTN OR RX. PT IS F/U WITH  
PCP TO MONITOR ELEVATED  
BP DUE TO + COVID 19 RESULT.  
DAO 17DEC2020

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|                                                            |   |
|------------------------------------------------------------|---|
| 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)       |   |

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Folder: Adverse Events

Form: Adverse Events (3)

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AEID

Adverse event

MYALGIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

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|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>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"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| <hr/>                                                                        |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |
| <hr/>                                                                        |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                         |                                                                                                                                                                                                                                                                                 |

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Folder: Adverse Events

Form: Adverse Events (4)

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|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | POLYARTHRALGIA                                                                                                                                                   |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Was this a Solicited Adverse Reaction?                         | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 19 SEP 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         | 24 SEP 2020                                                                                                                                                      |
| End time (00:00-23:59)                                         |                                                                                                                                                                  |
| AE End Date and Time (derived)                                 |                                                                                                                                                                  |
| Severity                                                       | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>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"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |

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|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 type="radio"/><br>Related <input checked="" type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Relationship to Study Procedure                                              | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                                                                                                           |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>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"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |                                                                                                                                                                                                                                                                                 |
| <hr/>                                                                        |                                                                                                                                                                                                                                                                                 |
| Narrative                                                                    |                                                                                                                                                                                                                                                                                 |
| <hr/>                                                                        |                                                                                                                                                                                                                                                                                 |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                         |                                                                                                                                                                                                                                                                                 |



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 12 Mar 2021 23:15:09

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 16:30:55

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Name of Medication CLARITIN

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (1)

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|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="checkbox"/>         |
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                    | Intralesional            | <input type="checkbox"/>         |
|                                                    | Intraperitoneal          | <input type="checkbox"/>         |
|                                                    | Nasal                    | <input type="checkbox"/>         |
|                                                    | Vaginal                  | <input type="checkbox"/>         |
|                                                    | Rectal                   | <input type="checkbox"/>         |
|                                                    | Intravenous              | <input type="checkbox"/>         |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                    | Intravenous Drip         | <input type="checkbox"/>         |
|                                                    | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2010              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication CERVICAL DISK HERNIATION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

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

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Form: Prior/Concomitant Medication and Vaccination (3)

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Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication CERVICAL DISK HERNIATION

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (3)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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Name of Medication TIZANADINE

Prophylaxis Yes ☐  
No ☒

Indication CERVICAL DISC HERNIATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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Name of Medication PERCOCET

Prophylaxis Yes ☐  
No ☒

Indication CERVICAL DISK HERNIATION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (5)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐  
No ☒

Indication WELLNESS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2015              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

Name of Medication FISH OIL

Prophylaxis Yes ☐

No ☒

Indication WELLNESS

Dose per administration 1000

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☒

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☐

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☒

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="radio"/>            |
|                                                    | Respiratory (Inhalation) | <input type="radio"/>            |
|                                                    | Intralesional            | <input type="radio"/>            |
|                                                    | Intraperitoneal          | <input type="radio"/>            |
|                                                    | Nasal                    | <input type="radio"/>            |
|                                                    | Vaginal                  | <input type="radio"/>            |
|                                                    | Rectal                   | <input type="radio"/>            |
|                                                    | Intravenous              | <input type="radio"/>            |
|                                                    | Intravenous Bolus        | <input type="radio"/>            |
|                                                    | Intravenous Drip         | <input type="radio"/>            |
|                                                    | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK                   | 2015                             |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE (SOLICITED AR -  
VACCINE #2)

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

|                                                    |                          |                                     |
|----------------------------------------------------|--------------------------|-------------------------------------|
|                                                    | 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)                           |                          | 20 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) 20 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"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19  
INFECTION

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

|                                                |                          |                                     |
|------------------------------------------------|--------------------------|-------------------------------------|
|                                                | 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)                       | 19 NOV 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|                                                | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         |                          | 26 NOV 2020                         |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|                                                | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               |                          |                                     |
| Interval Dosage Unit Number (derived)          |                          |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|                                                | 803                      | <input type="checkbox"/>            |
|                                                | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 243

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

|                                                    |                          |                                  |
|----------------------------------------------------|--------------------------|----------------------------------|
|                                                    | Intramuscular            | <input type="checkbox"/>         |
|                                                    | Respiratory (Inhalation) | <input type="checkbox"/>         |
|                                                    | Intralesional            | <input type="checkbox"/>         |
|                                                    | Intraperitoneal          | <input type="checkbox"/>         |
|                                                    | Nasal                    | <input type="checkbox"/>         |
|                                                    | Vaginal                  | <input type="checkbox"/>         |
|                                                    | Rectal                   | <input type="checkbox"/>         |
|                                                    | Intravenous              | <input type="checkbox"/>         |
|                                                    | Intravenous Bolus        | <input type="checkbox"/>         |
|                                                    | Intravenous Drip         | <input type="checkbox"/>         |
|                                                    | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 21 NOV 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?                                           | Yes                      | <input checked="" type="radio"/> |
|                                                    | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|                                                    | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|                                                    | 803                      | <input type="radio"/>            |
|                                                    | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

Name of Medication MRNA-1273 VACCINE

Prophylaxis Yes ☒  
No ☐

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 16:30:55

Generated On: 11 Aug 2021 22:22:23

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

US3342046

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Data signed:** (b) (4) 12 Mar 2021 23:15:09

**Generated On: 11 Aug 2021 22:22:23**

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

**If yes, please complete Concomitant Procedures form.**

---



US3342046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 29 Mar 2021 15:02:48

Generated On: 11 Aug 2021 22:22:23

Date of study discontinuation/completion (dd MMM yyyy) 04 JAN 2021

Reason for discontinuation

|                                                |                                     |
|------------------------------------------------|-------------------------------------|
| AE (specify)                                   | <input type="checkbox"/>            |
| SAE (specify)                                  | <input type="checkbox"/>            |
| Complete                                       | <input type="checkbox"/>            |
| Death                                          | <input type="checkbox"/>            |
| Lost To Follow-up                              | <input type="checkbox"/>            |
| Physician decision (specify)                   | <input type="checkbox"/>            |
| Pregnancy                                      | <input type="checkbox"/>            |
| Protocol deviation (specify)                   | <input checked="" type="checkbox"/> |
| Study Terminated By Sponsor                    | <input type="checkbox"/>            |
| Withdrawal of consent by participant (specify) | <input type="checkbox"/>            |
| Other                                          | <input type="checkbox"/>            |

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

SUBJECT REPORTED GETTING MODERNA VACCINE ON 28DEC2020 AND EXPRESSED THAT HE NO LONGER WANTED TO PARTICIPATE IN STUDY

If reason for discontinuation is Death, main cause of death

|               |                          |
|---------------|--------------------------|
| Adverse event | <input type="checkbox"/> |
| Unknown       | <input type="checkbox"/> |
| Other         | <input type="checkbox"/> |

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

|         |                          |
|---------|--------------------------|
| Yes     | <input type="checkbox"/> |
| No      | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US203-2020-MRNA-1273-P301000008                              |
| Serious                                                        | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | PAUL                                                             |
| Investigator's Last Name                                       | PICKRELL                                                         |
| Site Address: Street                                           |                                                                  |
| Site Address: City                                             |                                                                  |
| Site Address: State                                            |                                                                  |
| Site Address: Postal Code                                      |                                                                  |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 4                                                                |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US203-2020-MRNA-1273-P301000008                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | PAUL                                                             |
| Investigator's Last Name                                                                                                                                                                      | PICKRELL                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 01/DEC/2020 17:52                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US203-2020-MRNA-1273-P301000008                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | PAUL                                                             |
| Investigator's Last Name                                                                                                                                                                      | PICKRELL                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 15/JAN/2021 12:40                                                |
| 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                                                             |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US203-2020-MRNA-1273-P301000008                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | PAUL                                                             |
| Investigator's Last Name                                                                                                                                                                      | PICKRELL                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 09/FEB/2021 17:28                                                |
| 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                                                             |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Mar 2021 23:15:10

Generated On: 11 Aug 2021 22:22:23

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US203-2020-MRNA-1273-P301000008                              |
| Serious                                                                                                                                                                                       | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | PAUL                                                             |
| Investigator's Last Name                                                                                                                                                                      | PICKRELL                                                         |
| Site Address: Street                                                                                                                                                                          |                                                                  |
| Site Address: City                                                                                                                                                                            |                                                                  |
| Site Address: State                                                                                                                                                                           |                                                                  |
| Site Address: Postal Code                                                                                                                                                                     |                                                                  |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 12/MAR/2021 08:36                                                |
| 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

US3342046 (Prod: Tekton Research- Austin)

US3342046

Form: Participant Creation

Generated On: 11 Aug 2021 22:22:23

[Participant ID](#)

| Audit                     | User                                        | Time (GMT)           |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 02 May 2021 14:05:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                            | 31 Mar 2021 16:46:15 |
| User signature succeeded. | Paul Pickrell (b) (4)                       | 12 Mar 2021 23:15:11 |
| User entered 'US3342046'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 13:49:48 |



US3342046

Form: Participant Creation

Generated On: 11 Aug 2021 22:22:23

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 19:38:50 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 14:58:43 |

US3342046

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 19:38:50 |
| User entered '13 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 13:49:49 |

US3342046

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[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 12:50:24 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 19:38:50 |
| User entered 'Clinic (Clinic)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 14:58:43 |

US3342046

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'SCRN' | System           | 13 Aug 2020 14:58:43 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

Date of Birth (MMM yyyy)

| Audit                      | User                                        | Time (GMT)           |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)                       | 12 Mar 2021 23:15:11 |
| User entered (b) (6) 1979' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 13:49:50 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Age](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '41'         | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'YEARS' | System           | 13 Aug 2020 14:58:53 |



US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '41' | System           | 13 Aug 2020 14:59:04 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

Sex

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Male (M)'   | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Ethnicity](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

White

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '1'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Black](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Asian](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[American Indian or Alaska Native](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |



US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

If race is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

Unknown

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:22:23

[Not reported](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:58:53 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '13 Aug 2020' | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:04 |

US3342046

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'Aug 2020' | System           | 13 Aug 2020 14:59:04 |

US3342046

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '2020' | System           | 13 Aug 2020 14:59:04 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

[Protocol Version](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Amendment 2 (2)' | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:04 |



US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:04 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

If No, indicate reason for screen fail

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:04 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

If reason for screen fail is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:04 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

[Was this participant screened previously?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:04 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

[If Yes, previous participant number](#)

| Audit                     | User                                        | Time (GMT)           |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)                       | 12 Mar 2021 23:15:11 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 13:49:49 |

US3342046

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:22:23

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '1'  | System           | 13 Aug 2020 14:59:08 |

US3342046

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:22:23

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:08 |

US3342046

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:22:23

[Were any significant conditions reported?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:14 |



US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

[Condition](#)

| Audit                                                                                                                                                                        | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                                                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)   | 13 Aug 2020 15:01:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                 | Coder Import (b) (4)   | 13 Aug 2020 15:01:26 |
| Data point term sent to Coder                                                                                                                                                | System                 | 13 Aug 2020 15:00:18 |
| User entered 'seasonal allergies'                                                                                                                                            | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'un UNK 1980' | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'Jan 1980' | System           | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '1980' | System           | 13 Aug 2020 14:59:33 |



US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered empty. | System           | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered empty. | System           | 13 Aug 2020 14:59:33 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

[Condition](#)

| Audit                                                                                                                                                                                                                                                                                                         | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                                                                                                                                                                                                                                     | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Cervical disc herniation - version MedDRA\23.0. | Coder Import (b) (4)   | 13 Aug 2020 16:50:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                        | Coder Import (b) (4)   | 13 Aug 2020 16:50:18 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                 | System                 | 13 Aug 2020 15:02:24 |
| User entered 'cervical disk herniation'                                                                                                                                                                                                                                                                       | Eileen Euperio (b) (4) | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'un UNK 2013' | Eileen Euperio (b) (4) | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:01:28 |



US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'Jan 2013' | System           | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '2013' | System           | 13 Aug 2020 15:01:28 |

US3342046

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered empty. | System           | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered empty. | System           | 13 Aug 2020 15:01:28 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '13 Aug 2020' | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '08:45'      | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '13 Aug 2020 08:45' | System           | 13 Aug 2020 15:02:10 |



US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Height (xxx.x)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '183.0' cm   | (b) (4)<br>Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
| DataPoint set to visible. | (b) (4)<br>System                 | 13 Aug 2020 14:59:08 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Weight \(xxx.x\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '88.9' kg    | (b) (4)<br>Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
| DataPoint set to visible. | (b) (4)<br>System                 | 13 Aug 2020 14:59:08 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

BMI (xxx.x)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| Amendment Manager: User entered '26.54603' | System           | 16 Sep 2020 23:54:54 |
| User entered '26.5'                        | System           | 13 Aug 2020 15:02:10 |
| DataPoint set to visible.                  | System           | 13 Aug 2020 14:59:08 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'kg/m2'      | System           | 13 Aug 2020 15:02:10 |
| DataPoint set to visible. | System           | 13 Aug 2020 14:59:08 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 25 Aug 2020 23:18:12 |
| User entered '97.8' F                                                       | Andrew Bell (b) (4)    | 25 Aug 2020 23:18:12 |
|                                                                             | (b) (4)                |                      |
|                                                                             | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
|                                                                             | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                              | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered empty; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:18:12 |
| User entered 'Oral (Oral)'                             | Andrew Bell (b) (4)   | 13 Aug 2020 15:02:10 |
|                                                        | (b) (4)               |                      |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 25 Aug 2020 23:18:12 |
| User entered '75'                                                           | Andrew Bell (b) (4)    | 25 Aug 2020 23:18:12 |
|                                                                             | (b) (4)                |                      |
|                                                                             | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
|                                                                             | (b) (4)                |                      |



US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'bpm' | System           | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 25 Aug 2020 23:18:12 |
| User entered '16'                                                           | Andrew Bell (b) (4)    | 25 Aug 2020 23:18:12 |
|                                                                             | (b) (4)                |                      |
|                                                                             | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
|                                                                             | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'breaths/min' | System           | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 25 Aug 2020 23:18:12 |
| User entered '121'                                                          | Andrew Bell (b) (4)    | 25 Aug 2020 23:18:12 |
|                                                                             | (b) (4)                |                      |
|                                                                             | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
|                                                                             | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'mmHg' | System           | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 25 Aug 2020 23:18:12 |
| User entered '86'                                                           | Andrew Bell (b) (4)    | 25 Aug 2020 23:18:12 |
|                                                                             | (b) (4)                |                      |
|                                                                             | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:10 |
|                                                                             | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'mmHg' | System           | 13 Aug 2020 15:02:10 |

US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
|                   |                  |                      |



US3342046

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
|                   |                  |                      |

US3342046

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

[Was the physical examination performed?](#)

| Audit                                                      | User                   | Time (GMT)           |
|------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)                |                      |
|                                                            | Morgan Schulle (b) (4) | 18 Sep 2020 15:24:13 |
| User entered 'No (N)' reason for change: Data Entry Error  | (b) (4)                |                      |
|                                                            | Morgan Schulle (b) (4) | 18 Sep 2020 15:23:57 |
| User entered 'Yes (Y)'                                     | (b) (4)                |                      |
|                                                            | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:19 |
|                                                            | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

Date of examination (dd MMM yyyy)

| Audit                                                                                                                                    | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                        | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                                                                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '13 Aug 2020' reason for change: Data Entry Error                                                                           | (b) (4)                |                      |
|                                                                                                                                          | Morgan Schulle (b) (4) | 18 Sep 2020 15:24:13 |
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | (b) (4)                |                      |
|                                                                                                                                          | System                 | 18 Sep 2020 15:23:57 |
| User entered empty; reason for change Data Entry Error                                                                                   | Morgan Schulle (b) (4) | 18 Sep 2020 15:23:57 |
|                                                                                                                                          | (b) (4)                |                      |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System                 | 16 Sep 2020 14:54:58 |
| User entered '13 Aug 2020'                                                                                                               | Eileen Euperio (b) (4) | 13 Aug 2020 15:02:19 |
|                                                                                                                                          | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |



US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:22:23**

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

Other

| Audit                                                      | User                   | Time (GMT)           |
|------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)                | 13 Aug 2020 15:03:37 |
| User entered 'No (N)'                                      | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |
|                                                            | (b) (4)                |                      |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[Specify](#)

| Audit                                                                                                                                                           | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                               | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                                                                                       | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User closed query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System). | (b) (4)<br>System                 | 13 Aug 2020 15:03:37 |
| User opened query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:03:27 |
| User entered 'engineer inspector, works in office and travels to ~20 homes daily for work'                                                                      | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:03:27 |



US3342046

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

**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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

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 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '1'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

Other

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |

US3342046

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:22:23

[Specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 15:03:27 |



US3342046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 15:04:33 |

US3342046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '13 Aug 2020' | Eileen Euperio (b) (4) | 13 Aug 2020 15:04:33 |

US3342046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[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 12:50:24 |
| User signature succeeded.      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Clinic (Clinic)' | Eileen Euperio (b) (4) | 13 Aug 2020 15:04:33 |

US3342046

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'VISIT1' | System           | 13 Aug 2020 15:04:33 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                                        | Time (GMT)           |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)                       | 12 Mar 2021 23:15:22 |
| User entered '13 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 14:19:45 |

US3342046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

[What was the participant's randomization number?](#)

| Audit                                                                                                      | User                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                                                                          | (b) (4), (b) (6)                 | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                                  | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:22 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4)<br>System                | 21 Aug 2020 04:06:33 |
| Amendment Manager: Data point set to conformant.                                                           | System                           | 21 Aug 2020 04:06:33 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                           | 13 Aug 2020 14:19:45 |
| User entered '103758' (non-conformant).                                                                    | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 14:19:45 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

[In what Cohort was the participant enrolled?](#)

| Audit                                                 | User                                        | Time (GMT)           |
|-------------------------------------------------------|---------------------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                            | 28 Apr 2021 12:50:24 |
| User signature succeeded.                             | Paul Pickrell (b) (4)                       | 12 Mar 2021 23:15:22 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 13 Aug 2020 14:19:45 |

US3342046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 13 Aug 2020 22:33:36 |



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | Andrew Bell (b) (4)   | 13 Aug 2020 22:33:36 |

US3342046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

Severe obesity (body mass index > or = 40kg/m2

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:33:36 |

US3342046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:33:36 |

US3342046

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

[Liver Disease](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:33:36 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:22:23

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit                                        | User                  | Time (GMT)           |
|----------------------------------------------|-----------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                    | Paul Pickrell (b) (4) | 29 Mar 2021 15:02:48 |
| User entered 'No (N)'                        | Ethan Shotton (b) (4) | 22 Mar 2021 15:30:41 |
| Amendment Manager: DataPoint set to visible. | System                | 19 Sep 2020 10:19:27 |
| Amendment Manager inserted this DataPoint.   | System                | 19 Sep 2020 06:57:55 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:23

Height

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:17:42 |
| User entered '183.0' cm                                                     | Andrew Bell (b) (4)   | 13 Aug 2020 15:05:50 |
|                                                                             | (b) (4)               |                      |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:23

Weight

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:17:42 |
| User entered '88.9' kg                                                      | Andrew Bell (b) (4)   | 13 Aug 2020 15:05:50 |
|                                                                             | (b) (4)               |                      |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:23

[Height](#)

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:17:42 |
| User entered '183.0' cm                                                     | Andrew Bell (b) (4)   | 13 Aug 2020 15:05:50 |
|                                                                             | (b) (4)               |                      |



US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:23

Weight

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:17:42 |
| User entered '88.9' kg                                                      | Andrew Bell (b) (4)   | 13 Aug 2020 15:05:50 |
|                                                                             | (b) (4)               |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Timepoint](#)

| Audit                                            | User                   | Time (GMT)           |
|--------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                  | (b) (4)                |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '13 Aug 2020' | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '08:45'      | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '13 Aug 2020 08:45' | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '97.8' F     | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                                                                     | User                   | Time (GMT)           |
|---------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                 | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)                | 13 Aug 2020 22:33:58 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error            | System                 | 13 Aug 2020 22:33:58 |
| User opened query 'Data is required. Please provide.' (Site from System). | Andrew Bell (b) (4)    | 13 Aug 2020 22:33:58 |
| User entered empty.                                                       | (b) (4)                | 13 Aug 2020 15:05:50 |
|                                                                           | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                           | (b) (4)                |                      |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '78'         | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'bpm' | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '16'         | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'breaths/min' | System           | 13 Aug 2020 15:05:50 |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '121'        | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'mmHg' | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '86'         | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'mmHg' | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:23

[Height](#)

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:17:42 |
| User entered '183.0' cm                                                     | Andrew Bell (b) (4)   | 13 Aug 2020 15:05:50 |
|                                                                             | (b) (4)               |                      |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:22:23

Weight

| Audit                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 25 Aug 2020 23:17:42 |
| User entered '88.9' kg                                                      | Andrew Bell (b) (4)   | 13 Aug 2020 15:05:50 |
|                                                                             | (b) (4)               |                      |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Timepoint](#)

| Audit                                              | User                              | Time (GMT)           |
|----------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:05:50 |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Date of assessment (dd MMM yyyy)

| Audit                                                                     | User                   | Time (GMT)           |
|---------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                 | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System         | 13 Aug 2020 22:34:53 |
| User entered '13 Aug 2020' reason for change: Data Entry Error            | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System         | 13 Aug 2020 15:05:50 |
| User entered empty.                                                       | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                           | (b) (4)                |                      |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                                                                                                                                                                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                        | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                                                                                                                                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).                                                 | (b) (4)<br>(b) (4), (b) (6)       | 17 Aug 2020 10:32:22 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol 30 minute assessment required.' (Site from System). | Tiffany Lemuz (b) (4)             | 14 Aug 2020 19:16:43 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).                                                 | System                            | 13 Aug 2020 22:34:53 |
| User closed query 'Data is required. Please provide.' (Site from System).                                                                                                                                | System                            | 13 Aug 2020 22:34:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System).                                                                                                             | System                            | 13 Aug 2020 22:34:53 |
| User entered '10:15' reason for change: Data Entry Error                                                                                                                                                 | Andrew Bell (b) (4)<br>(b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System).                                                                                                                                | System                            | 13 Aug 2020 15:05:50 |
| User entered empty.                                                                                                                                                                                      | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '13 Aug 2020 10:15' | System           | 13 Aug 2020 22:34:53 |
| User entered empty.              | System           | 13 Aug 2020 15:05:50 |



US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 22:34:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                        | 13 Aug 2020 22:34:53 |
| User entered '98.0' F reason for change: Data Entry Error                                    | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 15:05:50 |
| User entered empty.                                                                          | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                                              | (b) (4)                |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                                                                     | User                   | Time (GMT)           |
|---------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                 | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)                | 13 Aug 2020 22:34:53 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error            | System                 | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User entered empty.                                                       | (b) (4)                | 13 Aug 2020 15:05:50 |
|                                                                           | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                           | (b) (4)                |                      |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)<br>Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 22:34:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                        | 13 Aug 2020 22:34:53 |
| User entered '66' reason for change: Data Entry Error                                        | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 15:05:50 |
| User entered empty.                                                                          | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                                              | (b) (4)                |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'bpm'  | System           | 13 Aug 2020 22:34:53 |
| User entered empty. | System           | 13 Aug 2020 15:05:50 |

US3342046

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 22:34:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                        | 13 Aug 2020 22:34:53 |
| User entered '16' reason for change: Data Entry Error                                        | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 15:05:50 |
| User entered empty.                                                                          | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                                              | (b) (4)                |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'breaths/min' | System           | 13 Aug 2020 22:34:53 |
| User entered empty.        | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 22:34:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). |                        | 13 Aug 2020 22:34:53 |
| User entered '122' reason for change: Data Entry Error                                       | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4) System         | 13 Aug 2020 15:05:50 |
| User entered empty.                                                                          | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                                              | (b) (4)                |                      |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'mmHg' | System           | 13 Aug 2020 22:34:53 |
| User entered empty. | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 13 Aug 2020 22:34:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 13 Aug 2020 22:34:53 |
| User entered '83' reason for change: Data Entry Error                                        | Andrew Bell (b) (4)    | 13 Aug 2020 22:34:53 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 13 Aug 2020 15:05:50 |
| User entered empty.                                                                          | Eileen Euperio (b) (4) | 13 Aug 2020 15:05:50 |
|                                                                                              | (b) (4)                |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'mmHg' | System           | 13 Aug 2020 22:34:53 |
| User entered empty. | System           | 13 Aug 2020 15:05:50 |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

[Was the physical examination performed?](#)

| Audit                                                     | User                   | Time (GMT)           |
|-----------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                 | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)                | 21 Aug 2020 21:19:03 |
| User entered 'Yes (Y)'                                    | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:00 |
|                                                           | (b) (4)                |                      |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

Date of examination (dd MMM yyyy)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.                              | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty; reason for change Data Entry Error | (b) (4)                | 21 Aug 2020 21:19:03 |
| User entered '13 Aug 2020'                             | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:00 |
|                                                        | (b) (4)                |                      |

US3342046

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[Was study treatment given?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:22 |



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '13 Aug 2020' | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '09:45'      | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '13 Aug 2020 09:45' | System           | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[Which arm was used to give treatment?](#)

| Audit                              | User                   | Time (GMT)           |
|------------------------------------|------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)       | 28 Apr 2021 12:50:24 |
| User signature succeeded.          | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Left Arm (LEFT ARM)' | Eileen Euperio (b) (4) | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'ONCE' | System           | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered 'INTRAMUSCULAR' | System           | 13 Aug 2020 15:06:22 |

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Andrew Bell (b) (4)   | 13 Aug 2020 22:36:07 |



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

Collection date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered '13 Aug 2020' | Andrew Bell (b) (4)   | 13 Aug 2020 22:36:07 |

US3342046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00-23:59)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered '09:17'      | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:36:07 |

US3342046

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '13 Aug 2020 09:17' | System           | 13 Aug 2020 22:36:07 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:22:23

Collection date (dd MMM yyyy)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered '13 Aug 2020' | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:36:19 |

US3342046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

[Lab Test](#)

| Audit                                                        | User                           | Time (GMT)           |
|--------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Andrew Bell (b) (4)<br>(b) (4) | 13 Aug 2020 22:36:19 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:36:19 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00 - 23:59)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4)          | 12 Mar 2021 23:15:22 |
| User entered '09:20'      | (b) (4)<br>Andrew Bell (b) (4) | 13 Aug 2020 22:36:19 |

US3342046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '13 Aug 2020 09:20' | System           | 13 Aug 2020 22:36:19 |



US3342046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

[Lab Test](#)

| Audit                                                        | User                           | Time (GMT)           |
|--------------------------------------------------------------|--------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)               | 28 Apr 2021 12:50:24 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Andrew Bell (b) (4)<br>(b) (4) | 13 Aug 2020 22:36:19 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                                                                                  | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 24 Aug 2020 17:02:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 24 Aug 2020 17:02:33 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Stefanie Mott (b) (4) | 24 Aug 2020 17:02:33 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 13 Aug 2020 22:36:19 |
| User entered empty.                                                                    | Andrew Bell (b) (4)   | 13 Aug 2020 22:36:19 |

US3342046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00 - 23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered empty.       | Andrew Bell (b) (4)   | 13 Aug 2020 22:36:19 |

US3342046

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered empty. | System           | 13 Aug 2020 22:36:19 |

US3342046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | Andrew Bell (b) (4)   | 13 Aug 2020 22:36:25 |

US3342046

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '1'  | System           | 13 Aug 2020 22:36:25 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                                   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:18:13', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3d9a8fb4-d07c-4dd7-9d26-5929756a5d74' User entered 'Yes (Y)' | System           | 13 Aug 2020 15:18:35 |
|                                                                                                                                                                                                                                                                                       | System           | 13 Aug 2020 15:18:35 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:18:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3d9a8fb4-d07c-4dd7-9d26-5929756a5d74' User entered '98.0' | System           | 13 Aug 2020 15:18:35 |
|                                                                                                                                                                                                                                                                                    | System           | 13 Aug 2020 15:18:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:18:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3d9a8fb4-d07c-4dd7-9d26-5929756a5d74' | System           | 13 Aug 2020 15:18:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 13 Aug 2020 15:18:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:18:34', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3d9a8fb4-d07c-4dd7-9d26-5929756a5d74' User entered '13 Aug 2020 10:18' | System           | 13 Aug 2020 15:18:35 |
|                                                                                                                                                                                                                                                                                                 | System           | 13 Aug 2020 15:18:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 10:05' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 12:35' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 1, after vaccination (at home)' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:43', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f98c9dc8-21fa-4785-a139-0c7fec7c0daa' User entered 'Yes (Y)' | System           | 14 Aug 2020 00:27:55 |
|                                                                                                                                                                                                                                                                                       | System           | 14 Aug 2020 00:27:55 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:47', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f98c9dc8-21fa-4785-a139-0c7fec7c0daa' User entered '98.1' | System           | 14 Aug 2020 00:27:55 |
|                                                                                                                                                                                                                                                                                    | System           | 14 Aug 2020 00:27:55 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f98c9dc8-21fa-4785-a139-0c7fec7c0daa' | System           | 14 Aug 2020 00:27:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 14 Aug 2020 00:27:55 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:52', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f98c9dc8-21fa-4785-a139-0c7fec7c0daa' User entered '13 Aug 2020 19:27' | System           | 14 Aug 2020 00:27:55 |
|                                                                                                                                                                                                                                                                                                 | System           | 14 Aug 2020 00:27:55 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 13:30' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '14 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 2' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:09:47', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'a4a23dce-41a8-4e3f-8b95-c6e55cdb9017' User entered 'Yes (Y)' | System           | 14 Aug 2020 23:09:57 |
|                                                                                                                                                                                                                                                                                       | System           | 14 Aug 2020 23:09:57 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:09:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'a4a23dce-41a8-4e3f-8b95-c6e55cdb9017' User entered '98.2' | System           | 14 Aug 2020 23:09:57 |
|                                                                                                                                                                                                                                                                                    | System           | 14 Aug 2020 23:09:57 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:09:53', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'a4a23dce-41a8-4e3f-8b95-c6e55cdb9017' User entered 'No (N)' | System           | 14 Aug 2020 23:09:57 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 23:09:57 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:09:55', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'a4a23dce-41a8-4e3f-8b95-c6e55cdb9017' | System           | 14 Aug 2020 23:09:57 |
| User entered '14 Aug 2020 18:09'                                                                                                                                                                                                                               | System           | 14 Aug 2020 23:09:57 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '14 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '15 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 3' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '701af640-2f51-4f86-b458-a4cbbe40836e' User entered 'Yes (Y)' | System           | 15 Aug 2020 23:38:39 |
|                                                                                                                                                                                                                                                                                       | System           | 15 Aug 2020 23:38:39 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '701af640-2f51-4f86-b458-a4cbbe40836e' User entered '98.5' | System           | 15 Aug 2020 23:38:39 |
|                                                                                                                                                                                                                                                                                    | System           | 15 Aug 2020 23:38:39 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:32', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '701af640-2f51-4f86-b458-a4cbbe40836e' User entered 'No (N)' | System           | 15 Aug 2020 23:38:39 |
|                                                                                                                                                                                                                                                                                      | System           | 15 Aug 2020 23:38:39 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:35', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '701af640-2f51-4f86-b458-a4cbbe40836e' User entered '15 Aug 2020 18:38' | System           | 15 Aug 2020 23:38:39 |
|                                                                                                                                                                                                                                                                                                 | System           | 15 Aug 2020 23:38:39 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '15 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 4' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:09', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '658c9ca6-5157-48c9-9811-b3acc60ff1af' User entered 'Yes (Y)' | System           | 16 Aug 2020 20:54:21 |
|                                                                                                                                                                                                                                                                                       | System           | 16 Aug 2020 20:54:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:14', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '658c9ca6-5157-48c9-9811-b3acc60ff1af' User entered '96.5' | System           | 16 Aug 2020 20:54:21 |
|                                                                                                                                                                                                                                                                                    | System           | 16 Aug 2020 20:54:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '658c9ca6-5157-48c9-9811-b3acc60ff1af' User entered 'No (N)' | System           | 16 Aug 2020 20:54:21 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Aug 2020 20:54:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '658c9ca6-5157-48c9-9811-b3acc60ff1af' User entered '16 Aug 2020 15:54' | System           | 16 Aug 2020 20:54:21 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Aug 2020 20:54:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 5' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c6514ff0-10cd-42b4-b0d8-fbf7afe46c74' User entered 'Yes (Y)' | System           | 17 Aug 2020 21:49:30 |
|                                                                                                                                                                                                                                                                                       | System           | 17 Aug 2020 21:49:30 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:23', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c6514ff0-10cd-42b4-b0d8-fbf7afe46c74' User entered '98.5' | System           | 17 Aug 2020 21:49:30 |
|                                                                                                                                                                                                                                                                                    | System           | 17 Aug 2020 21:49:30 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c6514ff0-10cd-42b4-b0d8-fbf7afe46c74' | System           | 17 Aug 2020 21:49:30 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 17 Aug 2020 21:49:30 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:28', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c6514ff0-10cd-42b4-b0d8-fbf7afe46c74' User entered '17 Aug 2020 16:49' | System           | 17 Aug 2020 21:49:30 |
|                                                                                                                                                                                                                                                                                                 | System           | 17 Aug 2020 21:49:30 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 6' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:06', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1d0c95e9-6378-4efa-b23e-68c1c4401997' | System           | 18 Aug 2020 21:53:17 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System           | 18 Aug 2020 21:53:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:12', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1d0c95e9-6378-4efa-b23e-68c1c4401997' User entered '98.4' | System           | 18 Aug 2020 21:53:17 |
|                                                                                                                                                                                                                                                                                    | System           | 18 Aug 2020 21:53:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:13', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1d0c95e9-6378-4efa-b23e-68c1c4401997' | System           | 18 Aug 2020 21:53:17 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 18 Aug 2020 21:53:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1d0c95e9-6378-4efa-b23e-68c1c4401997' | System           | 18 Aug 2020 21:53:17 |
| User entered '18 Aug 2020 16:53'                                                                                                                                                                                                                               | System           | 18 Aug 2020 21:53:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 7' | System           | 13 Aug 2020 15:06:22 |



US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:15:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c533013e-1cd0-4d95-989b-04bb3855ca08' User entered 'Yes (Y)' | System           | 20 Aug 2020 00:16:04 |
|                                                                                                                                                                                                                                                                                       | System           | 20 Aug 2020 00:16:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:15:57', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c533013e-1cd0-4d95-989b-04bb3855ca08' User entered '98.3' | System           | 20 Aug 2020 00:16:04 |
|                                                                                                                                                                                                                                                                                    | System           | 20 Aug 2020 00:16:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:15:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c533013e-1cd0-4d95-989b-04bb3855ca08' User entered 'No (N)' | System           | 20 Aug 2020 00:16:04 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Aug 2020 00:16:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:01', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c533013e-1cd0-4d95-989b-04bb3855ca08' User entered '19 Aug 2020 19:16' | System           | 20 Aug 2020 00:16:04 |
|                                                                                                                                                                                                                                                                                                 | System           | 20 Aug 2020 00:16:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                                   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:18:57', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94248f16-2688-466c-a479-eeb5f3c2b770' User entered 'None (1)' | System           | 13 Aug 2020 15:19:32 |
|                                                                                                                                                                                                                                                                                        | System           | 13 Aug 2020 15:19:32 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:18:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94248f16-2688-466c-a479-eeb5f3c2b770' User entered 'No (N)' | System           | 13 Aug 2020 15:19:32 |
|                                                                                                                                                                                                                                                                                      | System           | 13 Aug 2020 15:19:32 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:19:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94248f16-2688-466c-a479-eeb5f3c2b770' User entered 'No (N)' | System           | 13 Aug 2020 15:19:32 |
|                                                                                                                                                                                                                                                                                      | System           | 13 Aug 2020 15:19:32 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:19:09', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94248f16-2688-466c-a479-eeb5f3c2b770' | System           | 13 Aug 2020 15:19:32 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 13 Aug 2020 15:19:32 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:19:31', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94248f16-2688-466c-a479-eeb5f3c2b770' User entered '13 Aug 2020 10:19' | System           | 13 Aug 2020 15:19:32 |
|                                                                                                                                                                                                                                                                                                 | System           | 13 Aug 2020 15:19:32 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 10:05' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 12:35' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 1, after vaccination (at home)' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:26:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '96f2e600-611b-44aa-b8a4-c5fc9ac3b13f' User entered 'Does not interfere with activity (2)' | System           | 14 Aug 2020 00:27:17 |
|                                                                                                                                                                                                                                                                                                                    | System           | 14 Aug 2020 00:27:17 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:26:50', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '96f2e600-611b-44aa-b8a4-c5fc9ac3b13f' User entered 'No (N)' | System           | 14 Aug 2020 00:27:17 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 00:27:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:26:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '96f2e600-611b-44aa-b8a4-c5fc9ac3b13f' User entered 'No (N)' | System           | 14 Aug 2020 00:27:17 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 00:27:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:08', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '96f2e600-611b-44aa-b8a4-c5fc9ac3b13f' User entered 'None (1)' | System           | 14 Aug 2020 00:27:17 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:13', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '96f2e600-611b-44aa-b8a4-c5fc9ac3b13f' User entered '13 Aug 2020 19:27' | System           | 14 Aug 2020 00:27:17 |
|                                                                                                                                                                                                                                                                                                 | System           | 14 Aug 2020 00:27:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 13:30' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '14 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 2' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:01', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0ee4a7e4-1692-4dff-b2d8-2935b0d2a4cc' | System           | 14 Aug 2020 23:06:27 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:27 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:06', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0ee4a7e4-1692-4dff-b2d8-2935b0d2a4cc' User entered 'No (N)' | System           | 14 Aug 2020 23:06:27 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 23:06:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0ee4a7e4-1692-4dff-b2d8-2935b0d2a4cc' User entered 'No (N)' | System           | 14 Aug 2020 23:06:27 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 23:06:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0ee4a7e4-1692-4dff-b2d8-2935b0d2a4cc' | System           | 14 Aug 2020 23:06:27 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0ee4a7e4-1692-4dff-b2d8-2935b0d2a4cc' User entered '14 Aug 2020 18:06' | System           | 14 Aug 2020 23:06:27 |
|                                                                                                                                                                                                                                                                                                 | System           | 14 Aug 2020 23:06:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '14 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '15 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 3' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:38', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1a87856b-2e57-4460-8a61-ef42bc2b8120' User entered 'None (1)' | System           | 15 Aug 2020 23:38:47 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:38:47 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:41', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1a87856b-2e57-4460-8a61-ef42bc2b8120' User entered 'No (N)' | System           | 15 Aug 2020 23:38:47 |
|                                                                                                                                                                                                                                                                                      | System           | 15 Aug 2020 23:38:47 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1a87856b-2e57-4460-8a61-ef42bc2b8120' User entered 'No (N)' | System           | 15 Aug 2020 23:38:47 |
|                                                                                                                                                                                                                                                                                      | System           | 15 Aug 2020 23:38:47 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:43', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1a87856b-2e57-4460-8a61-ef42bc2b8120' User entered 'None (1)' | System           | 15 Aug 2020 23:38:47 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:38:47 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '1a87856b-2e57-4460-8a61-ef42bc2b8120' User entered '15 Aug 2020 18:38' | System           | 15 Aug 2020 23:38:47 |
|                                                                                                                                                                                                                                                                                                 | System           | 15 Aug 2020 23:38:47 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '15 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 4' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:22', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f105c710-c3cc-477a-8f19-6c1eeb214732' | System           | 16 Aug 2020 20:54:46 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:54:46 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f105c710-c3cc-477a-8f19-6c1eeb214732' | System           | 16 Aug 2020 20:54:46 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 16 Aug 2020 20:54:46 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:32', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f105c710-c3cc-477a-8f19-6c1eeb214732' | System           | 16 Aug 2020 20:54:46 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 16 Aug 2020 20:54:46 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f105c710-c3cc-477a-8f19-6c1eeb214732' | System           | 16 Aug 2020 20:54:46 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:54:46 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f105c710-c3cc-477a-8f19-6c1eeb214732' | System           | 16 Aug 2020 20:54:46 |
| User entered '16 Aug 2020 15:54'                                                                                                                                                                                                                               | System           | 16 Aug 2020 20:54:46 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 5' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ea52189c-395a-4aaa-823e-6f6c5afb7be0' User entered 'None (1)' | System           | 17 Aug 2020 21:49:41 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:41 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:34', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ea52189c-395a-4aaa-823e-6f6c5afb7be0' User entered 'No (N)' | System           | 17 Aug 2020 21:49:41 |
|                                                                                                                                                                                                                                                                                      | System           | 17 Aug 2020 21:49:41 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:35', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ea52189c-395a-4aaa-823e-6f6c5afb7be0' User entered 'No (N)' | System           | 17 Aug 2020 21:49:41 |
|                                                                                                                                                                                                                                                                                      | System           | 17 Aug 2020 21:49:41 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:38', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ea52189c-395a-4aaa-823e-6f6c5afb7be0' User entered 'None (1)' | System           | 17 Aug 2020 21:49:41 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:41 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:40', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ea52189c-395a-4aaa-823e-6f6c5afb7be0' User entered '17 Aug 2020 16:49' | System           | 17 Aug 2020 21:49:41 |
|                                                                                                                                                                                                                                                                                                 | System           | 17 Aug 2020 21:49:41 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 6' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9388517a-b6fc-4982-b2e1-7881b27274d4' User entered 'None (1)' | System           | 18 Aug 2020 21:53:35 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Aug 2020 21:53:35 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9388517a-b6fc-4982-b2e1-7881b27274d4' User entered 'No (N)' | System           | 18 Aug 2020 21:53:35 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Aug 2020 21:53:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9388517a-b6fc-4982-b2e1-7881b27274d4' User entered 'No (N)' | System           | 18 Aug 2020 21:53:35 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Aug 2020 21:53:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:29', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9388517a-b6fc-4982-b2e1-7881b27274d4' User entered 'None (1)' | System           | 18 Aug 2020 21:53:35 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Aug 2020 21:53:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:32', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9388517a-b6fc-4982-b2e1-7881b27274d4' User entered '18 Aug 2020 16:53' | System           | 18 Aug 2020 21:53:35 |
|                                                                                                                                                                                                                                                                                                 | System           | 18 Aug 2020 21:53:35 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 7' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:05', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7bdcac60-4059-4931-a8dc-dc2dea0789f3' | System           | 20 Aug 2020 00:16:17 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:17 |



US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:07', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7bdcac60-4059-4931-a8dc-dc2dea0789f3' User entered 'No (N)' | System           | 20 Aug 2020 00:16:17 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Aug 2020 00:16:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:08', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7bdcac60-4059-4931-a8dc-dc2dea0789f3' User entered 'No (N)' | System           | 20 Aug 2020 00:16:17 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Aug 2020 00:16:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:11', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7bdcac60-4059-4931-a8dc-dc2dea0789f3' | System           | 20 Aug 2020 00:16:17 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:14', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7bdcac60-4059-4931-a8dc-dc2dea0789f3' User entered '19 Aug 2020 19:16' | System           | 20 Aug 2020 00:16:17 |
|                                                                                                                                                                                                                                                                                                 | System           | 20 Aug 2020 00:16:17 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                                   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:19:50', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' | System           | 13 Aug 2020 15:20:21 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 13 Aug 2020 15:20:21 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:19:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' | System           | 13 Aug 2020 15:20:21 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:20:01', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' User entered 'None (0)' | System           | 13 Aug 2020 15:20:21 |
|                                                                                                                                                                                                                                                                                        | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:20:03', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' User entered 'None (0)' | System           | 13 Aug 2020 15:20:21 |
|                                                                                                                                                                                                                                                                                        | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:20:10', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' User entered 'None (0)' | System           | 13 Aug 2020 15:20:21 |
|                                                                                                                                                                                                                                                                                        | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:20:12', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' User entered 'None (0)' | System           | 13 Aug 2020 15:20:21 |
|                                                                                                                                                                                                                                                                                        | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:20:15', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' User entered 'No (N)' | System           | 13 Aug 2020 15:20:21 |
|                                                                                                                                                                                                                                                                                      | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T10:20:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c063ae18-6016-40c0-b3f6-d309b62ec667' User entered '13 Aug 2020 10:20' | System           | 13 Aug 2020 15:20:21 |
|                                                                                                                                                                                                                                                                                                 | System           | 13 Aug 2020 15:20:21 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 10:05' | System           | 13 Aug 2020 15:06:22 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 12:35' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 1, after vaccination (at home)' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'None (0)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'None (0)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:22', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'None (0)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'None (0)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'None (0)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'None (0)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 00:27:34 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered 'No (N)' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-13T19:27:32', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '44596b60-6ebf-4f52-8775-a28ddee5d9f4' User entered '13 Aug 2020 19:27' | System           | 14 Aug 2020 00:27:34 |
|                                                                                                                                                                                                                                                                                                 | System           | 14 Aug 2020 00:27:34 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '13 Aug 2020 13:30' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '14 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 2' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:28', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'None (0)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'None (0)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:33', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'None (0)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:43 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:34', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'None (0)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:36', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'None (0)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:37', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'None (0)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                        | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:39', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered 'No (N)' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                      | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-14T18:06:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '135405ba-6561-4559-9b86-5612c257dcc9' User entered '14 Aug 2020 18:06' | System           | 14 Aug 2020 23:06:43 |
|                                                                                                                                                                                                                                                                                                 | System           | 14 Aug 2020 23:06:43 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '14 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '15 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 3' | System           | 13 Aug 2020 15:06:22 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:48', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'None (0)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'None (0)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'None (0)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:52', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'None (0)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'None (0)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:55', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'None (0)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                        | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:38:57', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered 'No (N)' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                      | System           | 15 Aug 2020 23:39:04 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-15T18:39:00', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '01cefb3a-8f3e-4680-acaf-315f54d92dd0' User entered '15 Aug 2020 18:39' | System           | 15 Aug 2020 23:39:04 |
|                                                                                                                                                                                                                                                                                                 | System           | 15 Aug 2020 23:39:04 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '15 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 4' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:48', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' | System           | 16 Aug 2020 20:55:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' User entered 'None (0)' | System           | 16 Aug 2020 20:55:03 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' User entered 'None (0)' | System           | 16 Aug 2020 20:55:03 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:52', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' User entered 'None (0)' | System           | 16 Aug 2020 20:55:03 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:53', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' User entered 'None (0)' | System           | 16 Aug 2020 20:55:03 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:55:03 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' | System           | 16 Aug 2020 20:55:03 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:54:58', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' User entered 'No (N)' | System           | 16 Aug 2020 20:55:03 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-16T15:55:00', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '87a52e49-ff84-4a87-958c-fbd385b43796' | System           | 16 Aug 2020 20:55:03 |
| User entered '16 Aug 2020 15:55'                                                                                                                                                                                                                               | System           | 16 Aug 2020 20:55:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 5' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:44', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'None (0)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:46', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'None (0)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:59 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:47', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'None (0)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:48', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'None (0)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'None (0)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:52', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'None (0)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                        | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered 'No (N)' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                      | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-17T16:49:56', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '94d4a480-0527-4329-baad-6771d94940fa' User entered '17 Aug 2020 16:49' | System           | 17 Aug 2020 21:49:59 |
|                                                                                                                                                                                                                                                                                                 | System           | 17 Aug 2020 21:49:59 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 6' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:43', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' | System           | 18 Aug 2020 21:54:03 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:46', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' User entered 'None (0)' | System           | 18 Aug 2020 21:54:03 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' | System           | 18 Aug 2020 21:54:03 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' | System           | 18 Aug 2020 21:54:03 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' | System           | 18 Aug 2020 21:54:03 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'                                                                                                                                                                                      | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:56', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' | System           | 18 Aug 2020 21:54:03 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:53:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' User entered 'No (N)' | System           | 18 Aug 2020 21:54:03 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Aug 2020 21:54:03 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-18T16:54:01', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '504113c0-ba1f-4dd8-8f3b-41a626a3fe11' User entered '18 Aug 2020 16:54' | System           | 18 Aug 2020 21:54:03 |
|                                                                                                                                                                                                                                                                                                 | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 7' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:17', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'None (0)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'None (0)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'None (0)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'None (0)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:27 |



US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:20', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'None (0)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'None (0)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:23', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered 'No (N)' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-19T19:16:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f47fb205-d52d-4ab2-82b3-708e3ccdd6c4' User entered '19 Aug 2020 19:16' | System           | 20 Aug 2020 00:16:27 |
|                                                                                                                                                                                                                                                                                                 | System           | 20 Aug 2020 00:16:27 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Aug 2020 12:00' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Aug 2020 11:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 18 Aug 2020 21:54:03 |
| User entered 'Day 8' | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-21T06:41:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4afaa6d6-ad61-4f50-b514-3948a7dddd11' User entered 'No (N)' | System           | 21 Aug 2020 11:41:12 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Aug 2020 11:41:12 |



US3342046

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-08-21T06:41:10', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4afaa6d6-ad61-4f50-b514-3948a7dddd11' User entered '21 Aug 2020 06:41' | System           | 21 Aug 2020 11:41:12 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Aug 2020 11:41:12 |

US3342046

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Aug 2020 12:00' | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Aug 2020 11:59' | System           | 18 Aug 2020 21:54:03 |

US3342046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 20 Aug 2020 21:17:36 |

US3342046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered '20 Aug 2020' | Ethan Shotton (b) (4) | 20 Aug 2020 21:17:36 |

US3342046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 20 Aug 2020 21:17:36 |

US3342046

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered empty.       | Ethan Shotton (b) (4) | 20 Aug 2020 21:17:36 |

US3342046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 20 Aug 2020 21:17:40 |



US3342046

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '1'  | System           | 20 Aug 2020 21:17:40 |

US3342046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 27 Aug 2020 16:06:29 |

US3342046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered '27 Aug 2020' | Ethan Shotton (b) (4) | 27 Aug 2020 16:06:29 |

US3342046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 27 Aug 2020 16:06:29 |

US3342046

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered empty.       | Ethan Shotton (b) (4) | 27 Aug 2020 16:06:29 |

US3342046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 27 Aug 2020 16:06:33 |

US3342046

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '1'  | System           | 27 Aug 2020 16:06:33 |

US3342046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 03 Sep 2020 20:16:59 |



US3342046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered '3 Sep 2020' | Ethan Shotton (b) (4) | 03 Sep 2020 20:16:59 |

US3342046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 03 Sep 2020 20:16:59 |

US3342046

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered empty.       | Ethan Shotton (b) (4) | 03 Sep 2020 20:16:59 |

US3342046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 12:50:24 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 03 Sep 2020 20:17:04 |

US3342046

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:50:24 |
| User entered '1'  | System           | 03 Sep 2020 20:17:04 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:54:58 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '16 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:54:58 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.      | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered 'Clinic (Clinic)' | Morgan Schulle (b) (4) | 16 Sep 2020 14:54:58 |



US3342046

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'VISIT2' | System           | 16 Sep 2020 14:54:58 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Timepoint](#)

| Audit                                            | User                              | Time (GMT)           |
|--------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Date of assessment (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '16 Sep 2020' | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '09:30'      | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '16 Sep 2020 09:30' | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '97.4' F     | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Oral (Oral)' | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |



US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '81'         | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'bpm' | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '16'         | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'breaths/min' | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '142'        | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'mmHg' | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered '93'         | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'mmHg' | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Timepoint](#)

| Audit                                              | User                              | Time (GMT)           |
|----------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '16 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 16 Sep 2020 15:46:57 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 16 Sep 2020 15:46:57 |
| User entered '10:43' reason for change: Data Entry Error                                     | (b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 16 Sep 2020 14:56:49 |
| User entered empty.                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '16 Sep 2020 10:43' | System           | 16 Sep 2020 15:46:57 |
| User entered empty.              | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 16 Sep 2020 15:46:57 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 16 Sep 2020 15:46:57 |
| User entered '99.4' F reason for change: Data Entry Error                                    | (b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 16 Sep 2020 14:56:49 |
| User entered empty.                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User entered empty.                                            | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:56:49 |



US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 16 Sep 2020 15:46:57 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 16 Sep 2020 15:46:57 |
| User entered '74' reason for change: Data Entry Error                                        | (b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 16 Sep 2020 14:56:49 |
| User entered empty.                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |
|                                                                                              | (b) (4)                |                      |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'bpm'  | System           | 16 Sep 2020 15:46:57 |
| User entered empty. | System           | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 16 Sep 2020 15:46:57 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 16 Sep 2020 15:46:57 |
| User entered '16' reason for change: Data Entry Error                                        | (b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 16 Sep 2020 14:56:49 |
| User entered empty.                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'breaths/min' | System           | 16 Sep 2020 15:46:57 |
| User entered empty.        | System           | 16 Sep 2020 14:56:49 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 16 Sep 2020 15:46:57 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 16 Sep 2020 15:46:57 |
| User entered '134' reason for change: Data Entry Error                                       | (b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 16 Sep 2020 14:56:49 |
| User entered empty.                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'mmHg' | System           | 16 Sep 2020 15:46:57 |
| User entered empty. | System           | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                                                                                        | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                            | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 16 Sep 2020 15:46:57 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System                 | 16 Sep 2020 15:46:57 |
| User entered '92' reason for change: Data Entry Error                                        | (b) (4), (b) (6)       | 16 Sep 2020 15:46:57 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 16 Sep 2020 14:56:49 |
| User entered empty.                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:56:49 |



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'mmHg' | System           | 16 Sep 2020 15:46:57 |
| User entered empty. | System           | 16 Sep 2020 14:56:49 |

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

[Was the physical examination performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:57 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

Date of examination (dd MMM yyyy)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:56:57 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[Was study treatment given?](#)

| Audit                                                                                                                                                                                             | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                 | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                                                                                                                         | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | (b) (4)                | 16 Sep 2020 15:21:25 |
| Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System). | System                 | 16 Sep 2020 15:21:25 |
| User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | System                 | 16 Sep 2020 14:57:07 |
| User entered 'Yes (Y)'                                                                                                                                                                            | Morgan Schulle (b) (4) | 16 Sep 2020 14:57:07 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)                | 16 Sep 2020 14:57:07 |
|                           | Morgan Schulle (b) (4) |                      |
|                           | (b) (4)                |                      |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | Morgan Schulle (b) (4) | 16 Sep 2020 14:57:07 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 16 Sep 2020 14:57:07 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '16 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:07 |



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                        | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '10:11' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 16 Sep 2020 15:21:25 |
| User entered empty.                                      | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:57:07 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '16 Sep 2020 10:11' | System           | 16 Sep 2020 15:21:25 |
| User entered empty.              | System           | 16 Sep 2020 14:57:07 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[Which arm was used to give treatment?](#)

| Audit                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)       | 16 Sep 2020 15:21:25 |
| User entered empty.                                                    | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:57:07 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'ONCE' | System           | 16 Sep 2020 14:57:07 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:22:23

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'INTRAMUSCULAR' | System           | 16 Sep 2020 14:57:07 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:18 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

Collection date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '16 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:18 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00-23:59)

| Audit                                                                     | User                   | Time (GMT)           |
|---------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                 | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)                | 16 Sep 2020 15:26:37 |
| User entered '09:55' reason for change: Data Entry Error                  | System                 | 16 Sep 2020 15:26:37 |
| User opened query 'Data is required. Please provide.' (Site from System). | Morgan Schulle (b) (4) | 16 Sep 2020 14:57:18 |
| User entered empty.                                                       | (b) (4)                | 16 Sep 2020 14:57:18 |



US3342046

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '16 Sep 2020 09:55' | System           | 16 Sep 2020 15:26:37 |
| User entered empty.              | System           | 16 Sep 2020 14:57:18 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:22:23

Collection date (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered '16 Sep 2020' | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00 - 23:59)

| Audit                                                                                                                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                                                        | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.                                                                                                                                | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).             | (b) (4)                | 16 Sep 2020 15:26:52 |
| Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System). | System                 | 16 Sep 2020 15:26:52 |
| User entered '09:57' reason for change: Data Entry Error                                                                                                 | Morgan Schulle (b) (4) | 16 Sep 2020 15:26:52 |
| User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).             | (b) (4)                | 16 Sep 2020 14:57:35 |
| User entered empty.                                                                                                                                      | System                 | 16 Sep 2020 14:57:35 |
|                                                                                                                                                          | Morgan Schulle (b) (4) | 16 Sep 2020 14:57:35 |
|                                                                                                                                                          | (b) (4)                |                      |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:22:23

Collection date and time (derived)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '16 Sep 2020 09:57' | System           | 16 Sep 2020 15:26:52 |
| User entered empty.              | System           | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

[Lab Test](#)

| Audit                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                            | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Morgan Schulle (b) (4)<br>(b) (4) | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:35 |



US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:22 |
| User entered empty.       | Morgan Schulle (b) (4) | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:22:23

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered empty. | System           | 16 Sep 2020 14:57:35 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 16 Sep 2020 14:57:41 |

US3342046

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '1'  | System           | 16 Sep 2020 14:57:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                                   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:46:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c0707e1f-0f45-4230-9745-330a9c922517' User entered 'Yes (Y)' | System           | 16 Sep 2020 15:46:42 |
|                                                                                                                                                                                                                                                                                       | System           | 16 Sep 2020 15:46:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:46:31', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c0707e1f-0f45-4230-9745-330a9c922517' User entered '99.4' | System           | 16 Sep 2020 15:46:42 |
|                                                                                                                                                                                                                                                                                    | System           | 16 Sep 2020 15:46:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:46:36', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c0707e1f-0f45-4230-9745-330a9c922517' User entered 'No (N)' | System           | 16 Sep 2020 15:46:42 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 15:46:42 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:46:40', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'c0707e1f-0f45-4230-9745-330a9c922517' User entered '16 Sep 2020 10:46' | System           | 16 Sep 2020 15:46:42 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Sep 2020 15:46:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 10:31' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 13:01' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 1, after vaccination (at home)' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:08:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '290ab641-f84e-4075-8226-de98125067c6' User entered 'Yes (Y)' | System           | 16 Sep 2020 23:09:07 |
|                                                                                                                                                                                                                                                                                       | System           | 16 Sep 2020 23:09:07 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:08:58', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '290ab641-f84e-4075-8226-de98125067c6' User entered '96.7' | System           | 16 Sep 2020 23:09:07 |
|                                                                                                                                                                                                                                                                                    | System           | 16 Sep 2020 23:09:07 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:00', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '290ab641-f84e-4075-8226-de98125067c6' User entered 'No (N)' | System           | 16 Sep 2020 23:09:07 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 23:09:07 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '290ab641-f84e-4075-8226-de98125067c6' User entered '16 Sep 2020 18:09' | System           | 16 Sep 2020 23:09:07 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Sep 2020 23:09:07 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 13:56' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 2' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:33:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '99bb9ba7-cec6-4770-a5a8-cc89bd0d495d' User entered 'Yes (Y)' | System           | 18 Sep 2020 01:33:59 |
|                                                                                                                                                                                                                                                                                       | System           | 18 Sep 2020 01:33:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:33:53', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '99bb9ba7-cec6-4770-a5a8-cc89bd0d495d' User entered '97.5' | System           | 18 Sep 2020 01:33:59 |
|                                                                                                                                                                                                                                                                                    | System           | 18 Sep 2020 01:33:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:33:55', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '99bb9ba7-cec6-4770-a5a8-cc89bd0d495d' User entered 'No (N)' | System           | 18 Sep 2020 01:33:59 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Sep 2020 01:33:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:33:57', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '99bb9ba7-cec6-4770-a5a8-cc89bd0d495d' User entered '17 Sep 2020 20:33' | System           | 18 Sep 2020 01:33:59 |
|                                                                                                                                                                                                                                                                                                 | System           | 18 Sep 2020 01:33:59 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 3' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '28720785-395b-4674-8d33-44fc25500e99' User entered 'Yes (Y)' | System           | 19 Sep 2020 04:59:48 |
|                                                                                                                                                                                                                                                                                       | System           | 19 Sep 2020 04:59:48 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '28720785-395b-4674-8d33-44fc25500e99' User entered '97.9' | System           | 19 Sep 2020 04:59:48 |
|                                                                                                                                                                                                                                                                                    | System           | 19 Sep 2020 04:59:48 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:39', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '28720785-395b-4674-8d33-44fc25500e99' | System           | 19 Sep 2020 04:59:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 19 Sep 2020 04:59:48 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '28720785-395b-4674-8d33-44fc25500e99' User entered '18 Sep 2020 23:59' | System           | 19 Sep 2020 04:59:48 |
|                                                                                                                                                                                                                                                                                                 | System           | 19 Sep 2020 04:59:48 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 4' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:32', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b5ecd504-a22b-4ba5-bbbf-680b2625ca70' User entered 'Yes (Y)' | System           | 20 Sep 2020 00:36:42 |
|                                                                                                                                                                                                                                                                                       | System           | 20 Sep 2020 00:36:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:36', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b5ecd504-a22b-4ba5-bbbf-680b2625ca70' User entered '97.5' | System           | 20 Sep 2020 00:36:42 |
|                                                                                                                                                                                                                                                                                    | System           | 20 Sep 2020 00:36:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:38', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b5ecd504-a22b-4ba5-bbbf-680b2625ca70' User entered 'No (N)' | System           | 20 Sep 2020 00:36:42 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Sep 2020 00:36:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:40', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b5ecd504-a22b-4ba5-bbbf-680b2625ca70' User entered '19 Sep 2020 19:36' | System           | 20 Sep 2020 00:36:42 |
|                                                                                                                                                                                                                                                                                                 | System           | 20 Sep 2020 00:36:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 5' | System           | 16 Sep 2020 15:21:25 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:08', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '79de9464-e07c-4075-97c4-8df60bc31b3e' User entered 'Yes (Y)' | System           | 21 Sep 2020 01:55:24 |
|                                                                                                                                                                                                                                                                                       | System           | 21 Sep 2020 01:55:24 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '79de9464-e07c-4075-97c4-8df60bc31b3e' User entered '97.9' | System           | 21 Sep 2020 01:55:24 |
|                                                                                                                                                                                                                                                                                    | System           | 21 Sep 2020 01:55:24 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '79de9464-e07c-4075-97c4-8df60bc31b3e' User entered 'No (N)' | System           | 21 Sep 2020 01:55:24 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 01:55:24 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:20', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '79de9464-e07c-4075-97c4-8df60bc31b3e' User entered '20 Sep 2020 20:55' | System           | 21 Sep 2020 01:55:24 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 01:55:24 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 6' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:37', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '60e038b9-859a-46f2-b2d9-7e6919bb3f34' User entered 'Yes (Y)' | System           | 21 Sep 2020 22:58:49 |
|                                                                                                                                                                                                                                                                                       | System           | 21 Sep 2020 22:58:49 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '60e038b9-859a-46f2-b2d9-7e6919bb3f34' User entered '98.1' | System           | 21 Sep 2020 22:58:49 |
|                                                                                                                                                                                                                                                                                    | System           | 21 Sep 2020 22:58:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:44', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '60e038b9-859a-46f2-b2d9-7e6919bb3f34' User entered 'No (N)' | System           | 21 Sep 2020 22:58:49 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 22:58:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:47', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '60e038b9-859a-46f2-b2d9-7e6919bb3f34' User entered '21 Sep 2020 17:58' | System           | 21 Sep 2020 22:58:49 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 22:58:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '22 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 7' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:07', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'bbc21ebf-8a03-4cb9-a09f-14234205e919' User entered 'Yes (Y)' | System           | 22 Sep 2020 23:57:18 |
|                                                                                                                                                                                                                                                                                       | System           | 22 Sep 2020 23:57:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:11', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'bbc21ebf-8a03-4cb9-a09f-14234205e919' User entered '97.9' | System           | 22 Sep 2020 23:57:18 |
|                                                                                                                                                                                                                                                                                    | System           | 22 Sep 2020 23:57:18 |



US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:13', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'bbc21ebf-8a03-4cb9-a09f-14234205e919' User entered 'No (N)' | System           | 22 Sep 2020 23:57:18 |
|                                                                                                                                                                                                                                                                                      | System           | 22 Sep 2020 23:57:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:15', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'bbc21ebf-8a03-4cb9-a09f-14234205e919' User entered '22 Sep 2020 18:57' | System           | 22 Sep 2020 23:57:18 |
|                                                                                                                                                                                                                                                                                                 | System           | 22 Sep 2020 23:57:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '22 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                                   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:46:44', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cc357455-a69f-45e6-b1c9-9e192eddaed1' User entered 'None (1)' | System           | 16 Sep 2020 15:47:18 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:46:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cc357455-a69f-45e6-b1c9-9e192eddaed1' User entered 'No (N)' | System           | 16 Sep 2020 15:47:18 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 15:47:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:11', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cc357455-a69f-45e6-b1c9-9e192eddaed1' User entered 'No (N)' | System           | 16 Sep 2020 15:47:18 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 15:47:18 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:14', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cc357455-a69f-45e6-b1c9-9e192eddaed1' User entered 'None (1)' | System           | 16 Sep 2020 15:47:18 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cc357455-a69f-45e6-b1c9-9e192eddaed1' User entered '16 Sep 2020 10:47' | System           | 16 Sep 2020 15:47:18 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Sep 2020 15:47:18 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 10:31' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 13:01' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 1, after vaccination (at home)' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:05', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f93e214a-9acf-4d71-807b-af0ed14bc10f' User entered 'None (1)' | System           | 16 Sep 2020 23:09:20 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:20 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:12', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f93e214a-9acf-4d71-807b-af0ed14bc10f' User entered 'No (N)' | System           | 16 Sep 2020 23:09:20 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 23:09:20 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:13', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f93e214a-9acf-4d71-807b-af0ed14bc10f' User entered 'No (N)' | System           | 16 Sep 2020 23:09:20 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 23:09:20 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f93e214a-9acf-4d71-807b-af0ed14bc10f' User entered 'None (1)' | System           | 16 Sep 2020 23:09:20 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:20 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f93e214a-9acf-4d71-807b-af0ed14bc10f' User entered '16 Sep 2020 18:09' | System           | 16 Sep 2020 23:09:20 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Sep 2020 23:09:20 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 13:56' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 2' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:00', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '8f0be364-3c32-44f7-b780-fbfb6e38f495' | System           | 18 Sep 2020 01:34:13 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:13 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:03', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '8f0be364-3c32-44f7-b780-fbfb6e38f495' User entered 'No (N)' | System           | 18 Sep 2020 01:34:13 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Sep 2020 01:34:13 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:05', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '8f0be364-3c32-44f7-b780-fbfb6e38f495' User entered 'No (N)' | System           | 18 Sep 2020 01:34:13 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Sep 2020 01:34:13 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:07', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '8f0be364-3c32-44f7-b780-fbfb6e38f495' | System           | 18 Sep 2020 01:34:13 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:13 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:09', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '8f0be364-3c32-44f7-b780-fbfb6e38f495' User entered '17 Sep 2020 20:34' | System           | 18 Sep 2020 01:34:13 |
|                                                                                                                                                                                                                                                                                                 | System           | 18 Sep 2020 01:34:13 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 3' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'dbc4ce89-0f07-4913-b160-dc7d54e7c723' User entered 'None (1)' | System           | 19 Sep 2020 05:00:02 |
|                                                                                                                                                                                                                                                                                        | System           | 19 Sep 2020 05:00:02 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:47', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'dbc4ce89-0f07-4913-b160-dc7d54e7c723' User entered 'No (N)' | System           | 19 Sep 2020 05:00:02 |
|                                                                                                                                                                                                                                                                                      | System           | 19 Sep 2020 05:00:02 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'dbc4ce89-0f07-4913-b160-dc7d54e7c723' User entered 'No (N)' | System           | 19 Sep 2020 05:00:02 |
|                                                                                                                                                                                                                                                                                      | System           | 19 Sep 2020 05:00:02 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'dbc4ce89-0f07-4913-b160-dc7d54e7c723' User entered 'None (1)' | System           | 19 Sep 2020 05:00:02 |
|                                                                                                                                                                                                                                                                                        | System           | 19 Sep 2020 05:00:02 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'dbc4ce89-0f07-4913-b160-dc7d54e7c723' User entered '18 Sep 2020 23:59' | System           | 19 Sep 2020 05:00:02 |
|                                                                                                                                                                                                                                                                                                 | System           | 19 Sep 2020 05:00:02 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 4' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7cffb425-d071-4833-b82c-d5db1cff27a4' | System           | 20 Sep 2020 00:36:28 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:28 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:20', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7cffb425-d071-4833-b82c-d5db1cff27a4' User entered 'No (N)' | System           | 20 Sep 2020 00:36:28 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Sep 2020 00:36:28 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:22', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7cffb425-d071-4833-b82c-d5db1cff27a4' User entered 'No (N)' | System           | 20 Sep 2020 00:36:28 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Sep 2020 00:36:28 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7cffb425-d071-4833-b82c-d5db1cff27a4' User entered 'None (1)' | System           | 20 Sep 2020 00:36:28 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:28 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7cffb425-d071-4833-b82c-d5db1cff27a4' User entered '19 Sep 2020 19:36' | System           | 20 Sep 2020 00:36:28 |
|                                                                                                                                                                                                                                                                                                 | System           | 20 Sep 2020 00:36:28 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 5' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:23', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9b866a09-763a-4be9-b9d5-8f805e8c2a86' | System           | 21 Sep 2020 01:55:35 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 21 Sep 2020 01:55:35 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9b866a09-763a-4be9-b9d5-8f805e8c2a86' User entered 'No (N)' | System           | 21 Sep 2020 01:55:35 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 01:55:35 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9b866a09-763a-4be9-b9d5-8f805e8c2a86' User entered 'No (N)' | System           | 21 Sep 2020 01:55:35 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 01:55:35 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9b866a09-763a-4be9-b9d5-8f805e8c2a86' User entered 'None (1)' | System           | 21 Sep 2020 01:55:35 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 01:55:35 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:29', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '9b866a09-763a-4be9-b9d5-8f805e8c2a86' User entered '20 Sep 2020 20:55' | System           | 21 Sep 2020 01:55:35 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 01:55:35 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 6' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:50', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'aadf06bd-dd88-4fee-8100-1f830bc690a6' User entered 'None (1)' | System           | 21 Sep 2020 22:58:58 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:58:58 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'aadf06bd-dd88-4fee-8100-1f830bc690a6' User entered 'No (N)' | System           | 21 Sep 2020 22:58:58 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 22:58:58 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:52', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'aadf06bd-dd88-4fee-8100-1f830bc690a6' User entered 'No (N)' | System           | 21 Sep 2020 22:58:58 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 22:58:58 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:53', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'aadf06bd-dd88-4fee-8100-1f830bc690a6' User entered 'None (1)' | System           | 21 Sep 2020 22:58:58 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:58:58 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:55', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'aadf06bd-dd88-4fee-8100-1f830bc690a6' User entered '21 Sep 2020 17:58' | System           | 21 Sep 2020 22:58:58 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 22:58:58 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '22 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 7' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e3ce051f-059b-46cf-bb11-278ad7dd7916' | System           | 22 Sep 2020 23:57:33 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:23', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e3ce051f-059b-46cf-bb11-278ad7dd7916' User entered 'No (N)' | System           | 22 Sep 2020 23:57:33 |
|                                                                                                                                                                                                                                                                                      | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e3ce051f-059b-46cf-bb11-278ad7dd7916' User entered 'No (N)' | System           | 22 Sep 2020 23:57:33 |
|                                                                                                                                                                                                                                                                                      | System           | 22 Sep 2020 23:57:33 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e3ce051f-059b-46cf-bb11-278ad7dd7916' | System           | 22 Sep 2020 23:57:33 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:28', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e3ce051f-059b-46cf-bb11-278ad7dd7916' User entered '22 Sep 2020 18:57' | System           | 22 Sep 2020 23:57:33 |
|                                                                                                                                                                                                                                                                                                 | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '22 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                                                | User             | Time (GMT)           |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                                   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'None (0)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'None (0)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:23', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'None (0)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:38 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'None (0)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'None (0)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'None (0)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered 'No (N)' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T10:47:32', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '340bcac2-6960-44dc-8605-5c9f506d13f9' User entered '16 Sep 2020 10:47' | System           | 16 Sep 2020 15:47:38 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Sep 2020 15:47:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 10:31' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 13:01' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                             | User             | Time (GMT)           |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.                                | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 1, after vaccination (at home)' | System           | 16 Sep 2020 15:21:25 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'None (0)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:23', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'None (0)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'None (0)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'None (0)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'None (0)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'None (0)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                        | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:29', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered 'No (N)' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Sep 2020 23:09:38 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-16T18:09:31', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'e58e3685-e2b4-4982-a87b-5a70d61c3021' User entered '16 Sep 2020 18:09' | System           | 16 Sep 2020 23:09:38 |
|                                                                                                                                                                                                                                                                                                 | System           | 16 Sep 2020 23:09:38 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '16 Sep 2020 13:56' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 2' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:14', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' | System           | 18 Sep 2020 01:34:27 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:15', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered 'None (0)' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered 'None (0)' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:17', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered 'None (0)' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered 'None (0)' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:27 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:20', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered 'None (0)' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                        | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:22', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered 'No (N)' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                      | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-17T20:34:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'b164274e-3ca4-424e-8bbd-e83c6da6b72f' User entered '17 Sep 2020 20:34' | System           | 18 Sep 2020 01:34:27 |
|                                                                                                                                                                                                                                                                                                 | System           | 18 Sep 2020 01:34:27 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '17 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 3' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-18T23:59:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' | System           | 19 Sep 2020 05:00:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' User entered 'None (0)' | System           | 19 Sep 2020 05:00:41 |
|                                                                                                                                                                                                                                                                                        | System           | 19 Sep 2020 05:00:41 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:05', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' | System           | 19 Sep 2020 05:00:41 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:07', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' | System           | 19 Sep 2020 05:00:41 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:09', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' User entered 'None (0)' | System           | 19 Sep 2020 05:00:41 |
|                                                                                                                                                                                                                                                                                        | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:11', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' | System           | 19 Sep 2020 05:00:41 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:14', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' | System           | 19 Sep 2020 05:00:41 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T00:00:17', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '435c3400-d856-4846-8e1e-ebd0f8818f55' | System           | 19 Sep 2020 05:00:41 |
| User entered '19 Sep 2020 00:00'                                                                                                                                                                                                                               | System           | 19 Sep 2020 05:00:41 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '18 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 4' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:43', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'None (0)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:44', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'None (0)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'None (0)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:46', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'None (0)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:48', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'None (0)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'None (0)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                        | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered 'No (N)' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                      | System           | 20 Sep 2020 00:36:56 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-19T19:36:52', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4845567e-a576-4a34-9164-720a3c56d7f3' User entered '19 Sep 2020 19:36' | System           | 20 Sep 2020 00:36:56 |
|                                                                                                                                                                                                                                                                                                 | System           | 20 Sep 2020 00:36:56 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '19 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 5' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:37', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' | System           | 21 Sep 2020 01:55:54 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:39', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered 'None (0)' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:41', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered 'No interference with activity (1)' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:43', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered 'No interference with activity (1)' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 01:55:54 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered 'None (0)' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:46', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered 'None (0)' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered 'No (N)' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-20T20:55:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'd089802c-917a-47e6-9fe8-eb65013b3dc9' User entered '20 Sep 2020 20:55' | System           | 21 Sep 2020 01:55:54 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 01:55:54 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '20 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 6' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:58:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'None (0)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:59:10 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:00', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'None (0)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:01', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'None (0)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'None (0)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:03', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'None (0)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:04', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'None (0)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                        | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:06', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered 'No (N)' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                      | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-21T17:59:08', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0fcb8d38-44c0-44ea-98a1-6b88ed1d2175' User entered '21 Sep 2020 17:59' | System           | 21 Sep 2020 22:59:10 |
|                                                                                                                                                                                                                                                                                                 | System           | 21 Sep 2020 22:59:10 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '21 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '22 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 16 Sep 2020 15:21:25 |
| User entered 'Day 7' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:34', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' | System           | 22 Sep 2020 23:57:49 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**FATIGUE**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:36', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' User entered 'None (0)' | System           | 22 Sep 2020 23:57:49 |
|                                                                                                                                                                                                                                                                                        | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:39', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' | System           | 22 Sep 2020 23:57:49 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:40', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' User entered 'No interference with activity (1)' | System           | 22 Sep 2020 23:57:49 |
|                                                                                                                                                                                                                                                                                                                 | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:42', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' User entered 'None (0)' | System           | 22 Sep 2020 23:57:49 |
|                                                                                                                                                                                                                                                                                        | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:43', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' User entered 'None (0)' | System           | 22 Sep 2020 23:57:49 |
|                                                                                                                                                                                                                                                                                        | System           | 22 Sep 2020 23:57:49 |



US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' User entered 'No (N)' | System           | 22 Sep 2020 23:57:49 |
|                                                                                                                                                                                                                                                                                      | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-22T18:57:47', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '538fc194-0b70-4ed7-bfc1-cd7bcaaf19a6' User entered '22 Sep 2020 18:57' | System           | 22 Sep 2020 23:57:49 |
|                                                                                                                                                                                                                                                                                                 | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '22 Sep 2020 12:00' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 11:59' | System           | 16 Sep 2020 15:21:25 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:33 |
| User entered 'Day 8' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 11 Aug 2021 22:22:23

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

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:09', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7b8b2fb7-8c39-4591-9366-09f63a820660' | System           | 24 Sep 2020 00:58:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System           | 24 Sep 2020 00:58:15 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:13', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '7b8b2fb7-8c39-4591-9366-09f63a820660' User entered '23 Sep 2020 19:58' | System           | 24 Sep 2020 00:58:15 |
|                                                                                                                                                                                                                                                                                                 | System           | 24 Sep 2020 00:58:15 |

US3342046

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:33 |



US3342046

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:49 |
| User entered 'Day 8' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:22:23

Select one response below to indicate the intensity of your **HEADACHE**

| Audit                                                                                                                                                                                                                                                                                 | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4759eed-4152-4db3-91bd-8d30fed0e70e' User entered 'None (0)' | System           | 24 Sep 2020 00:58:20 |
|                                                                                                                                                                                                                                                                                       | System           | 24 Sep 2020 00:58:20 |

US3342046

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:18', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '4759eed-4152-4db3-91bd-8d30fed0e70e' User entered '23 Sep 2020 19:58' | System           | 24 Sep 2020 00:58:20 |
|                                                                                                                                                                                                                                                                                                | System           | 24 Sep 2020 00:58:20 |

US3342046

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:49 |
| User entered 'Day 8' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:22', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '623b8fcf-c8c4-4fd6-b954-50d2dd71018e' User entered 'No interference with activity (1)' | System           | 24 Sep 2020 00:58:29 |
|                                                                                                                                                                                                                                                                                                                 | System           | 24 Sep 2020 00:58:29 |



US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '623b8fcf-c8c4-4fd6-b954-50d2dd71018e' User entered '23 Sep 2020 19:58' | System           | 24 Sep 2020 00:58:29 |
|                                                                                                                                                                                                                                                                                                 | System           | 24 Sep 2020 00:58:29 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:49 |
| User entered 'Day 9' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-24T22:44:25', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'a15a4bca-855f-4cde-b48e-27013f1fa88f' User entered 'None (0)' | System           | 25 Sep 2020 03:44:34 |
|                                                                                                                                                                                                                                                                                        | System           | 25 Sep 2020 03:44:34 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-24T22:44:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'a15a4bca-855f-4cde-b48e-27013f1fa88f' User entered '24 Sep 2020 22:44' | System           | 25 Sep 2020 03:44:34 |
|                                                                                                                                                                                                                                                                                                 | System           | 25 Sep 2020 03:44:34 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '25 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:49 |



US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:49 |
| User entered 'Day 8' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:27', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'eceb3c84-c2ba-4528-92ed-440870854a3b' User entered 'No interference with activity (1)' | System           | 24 Sep 2020 00:58:31 |
|                                                                                                                                                                                                                                                                                                                 | System           | 24 Sep 2020 00:58:31 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:30', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'eceb3c84-c2ba-4528-92ed-440870854a3b' User entered '23 Sep 2020 19:58' | System           | 24 Sep 2020 00:58:31 |
|                                                                                                                                                                                                                                                                                                 | System           | 24 Sep 2020 00:58:31 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:49 |
| User entered 'Day 9' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-24T22:44:33', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ed154819-f173-4ddc-bd39-cddfc55c3109' User entered 'None (0)' | System           | 25 Sep 2020 03:44:42 |
|                                                                                                                                                                                                                                                                                        | System           | 25 Sep 2020 03:44:42 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-24T22:44:35', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'ed154819-f173-4ddc-bd39-cddfc55c3109' User entered '24 Sep 2020 22:44' | System           | 25 Sep 2020 03:44:42 |
|                                                                                                                                                                                                                                                                                                 | System           | 25 Sep 2020 03:44:42 |



US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '25 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:49 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:33 |
| User entered 'Day 8' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:33', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '37e48494-252e-4b0b-94f1-9ef7bf20b5af' User entered 'No (N)' | System           | 24 Sep 2020 00:58:39 |
|                                                                                                                                                                                                                                                                                      | System           | 24 Sep 2020 00:58:39 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-23T19:58:36', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '37e48494-252e-4b0b-94f1-9ef7bf20b5af' User entered '23 Sep 2020 19:58' | System           | 24 Sep 2020 00:58:39 |
|                                                                                                                                                                                                                                                                                                 | System           | 24 Sep 2020 00:58:39 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '23 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.   | System           | 22 Sep 2020 23:57:33 |
| User entered 'Day 9' | System           | 22 Sep 2020 23:57:33 |



US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-24T22:44:38', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'bbcc8a0b-d3aa-4509-a646-b088b9c4ff43' User entered 'No (N)' | System           | 25 Sep 2020 03:44:46 |
|                                                                                                                                                                                                                                                                                      | System           | 25 Sep 2020 03:44:46 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-09-24T22:44:40', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'bbcc8a0b-d3aa-4509-a646-b088b9c4ff43' User entered '24 Sep 2020 22:44' | System           | 25 Sep 2020 03:44:46 |
|                                                                                                                                                                                                                                                                                                 | System           | 25 Sep 2020 03:44:46 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '24 Sep 2020 12:00' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:22:23

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| User entered '25 Sep 2020 11:59' | System           | 22 Sep 2020 23:57:33 |

US3342046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 23 Sep 2020 19:56:22 |

US3342046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered '23 Sep 2020' | Ethan Shotton (b) (4) | 23 Sep 2020 19:56:22 |

US3342046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 23 Sep 2020 19:56:22 |

US3342046

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered empty.       | Ethan Shotton (b) (4) | 23 Sep 2020 19:56:22 |



US3342046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 23 Sep 2020 19:56:25 |

US3342046

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '1'  | System           | 23 Sep 2020 19:56:25 |

US3342046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 30 Sep 2020 16:14:24 |

US3342046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered '30 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 16:14:24 |

US3342046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded.                  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 16:14:24 |

US3342046

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered empty.       | (b) (4), (b) (6)      | 30 Sep 2020 16:14:24 |

US3342046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 16:14:13 |

US3342046

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '1'  | System           | 30 Sep 2020 16:14:13 |



US3342046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 08 Oct 2020 16:16:22 |

US3342046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered '8 Oct 2020' | Ethan Shotton (b) (4) | 08 Oct 2020 16:16:22 |

US3342046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4) | 08 Oct 2020 16:16:22 |

US3342046

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered empty.       | Ethan Shotton (b) (4) | 08 Oct 2020 16:16:22 |

US3342046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 08 Oct 2020 16:16:27 |

US3342046

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '1'  | System           | 08 Oct 2020 16:16:27 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:46:49 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '14 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:46:49 |



US3342046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded.      | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:46:49 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered 'VISIT3' | System           | 14 Oct 2020 13:46:49 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '14 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '08:15'      | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 16:50:56 |
| User entered '14 Oct 2020 08:15' | System           | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '98.5' F     | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |



US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '65'         | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 29 Apr 2021 16:50:56 |
| User entered 'bpm' | System           | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '13'         | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 29 Apr 2021 16:50:56 |
| User entered 'breaths/min' | System           | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '141'        | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 16:50:56 |
| User entered 'mmHg' | System           | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:50:56 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered '100'        | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:28 |



US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 16:50:56 |
| User entered 'mmHg' | System           | 14 Oct 2020 13:47:28 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Height \(derived\)](#)

| Audit             | User                           | Time (GMT)           |
|-------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6)<br>[REDACTED] | 29 Apr 2021 16:50:56 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:50:56 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:31 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

Date of examination (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:31 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tiffany Lemuz (b) (4) | 28 Oct 2020 15:16:04 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

Collection date (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:22 |
| User entered '14 Oct 2020' | (b) (4)<br>Tiffany Lemuz (b) (4) | 28 Oct 2020 15:16:04 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

Collection time (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:22 |
| User entered '08:47'      | (b) (4)<br>Tiffany Lemuz (b) (4) | 28 Oct 2020 15:16:04 |



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Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:22:23

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '14 Oct 2020 08:47' | System           | 28 Oct 2020 15:16:04 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:22 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Oct 2020 13:47:38 |

US3342046

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '1'  | System           | 14 Oct 2020 13:47:38 |

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.    | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 64' | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-10-16T09:24:55', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '63a757f2-e864-4fa2-870d-416e992c5c0c' User entered 'No (N)' | System           | 16 Oct 2020 14:25:50 |
|                                                                                                                                                                                                                                                                                      | System           | 16 Oct 2020 14:25:50 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-10-16T09:25:45', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '63a757f2-e864-4fa2-870d-416e992c5c0c' | System           | 16 Oct 2020 14:25:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 16 Oct 2020 14:25:50 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-10-16T09:25:48', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '63a757f2-e864-4fa2-870d-416e992c5c0c' User entered '16 Oct 2020 09:25:48' | System           | 16 Oct 2020 14:25:50 |
|                                                                                                                                                                                                                                                                                                    | System           | 16 Oct 2020 14:25:50 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.               | System           | 13 Aug 2020 15:06:22 |
| User entered '13 Oct 2020 00:01' | System           | 13 Aug 2020 15:06:22 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.               | System           | 13 Aug 2020 15:06:22 |
| User entered '17 Oct 2020 23:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.    | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 71' | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                                                | User             | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                    | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-10-22T12:03:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0940e638-e8a4-4433-8ad8-cffe9acb014b' User entered 'No (N)' | System           | 22 Oct 2020 17:03:16 |
|                                                                                                                                                                                                                                                                                      | System           | 22 Oct 2020 17:03:16 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-10-22T12:03:04', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0940e638-e8a4-4433-8ad8-cffe9acb014b' | System           | 22 Oct 2020 17:03:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 22 Oct 2020 17:03:16 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-10-22T12:03:07', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '0940e638-e8a4-4433-8ad8-cffe9acb014b' User entered '22 Oct 2020 12:03:07' | System           | 22 Oct 2020 17:03:16 |
|                                                                                                                                                                                                                                                                                                    | System           | 22 Oct 2020 17:03:16 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.               | System           | 13 Aug 2020 15:06:22 |
| User entered '20 Oct 2020 00:01' | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.               | System           | 13 Aug 2020 15:06:22 |
| User entered '24 Oct 2020 23:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |
| Data entry locked.                        | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 78'                     | System           | 13 Aug 2020 15:06:22 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

**US3342046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

**US3342046**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |
| Data entry locked.                        | System           | 13 Aug 2020 15:06:22 |
| User entered '27 Oct 2020 00:01'          | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |
| Data entry locked.                        | System           | 13 Aug 2020 15:06:22 |
| User entered '31 Oct 2020 23:59'          | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.    | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 92' | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                          | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-10T17:54:49', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cca9fefa-0bde-42e9-91b9-7b47da2ddcc6' | System           | 10 Nov 2020 23:54:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 10 Nov 2020 23:54:56 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                       | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                           | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-10T17:54:51', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cca9fefaf0bde42e991b97b47da2ddcc6' | System           | 10 Nov 2020 23:54:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                       | System           | 10 Nov 2020 23:54:56 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-10T17:54:54', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'cca9fefa-0bde-42e9-91b9-7b47da2ddcc6' User entered '10 Nov 2020 17:54:54' | System           | 10 Nov 2020 23:54:56 |
|                                                                                                                                                                                                                                                                                                    | System           | 10 Nov 2020 23:54:56 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.               | System           | 13 Aug 2020 15:06:22 |
| User entered '10 Nov 2020 00:01' | System           | 13 Aug 2020 15:06:22 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 14:25:22 |
| Data entry locked.               | System           | 13 Aug 2020 15:06:22 |
| User entered '14 Nov 2020 23:59' | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |
| Data entry locked.                        | System           | 13 Aug 2020 15:06:22 |
| User entered 'Day 99'                     | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |
| Data entry locked.                        | System           | 13 Aug 2020 15:06:22 |
| User entered '17 Nov 2020 00:01'          | System           | 13 Aug 2020 15:06:22 |

US3342046

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 05:48:17 |
| Data entry locked.                        | System           | 13 Aug 2020 15:06:22 |
| User entered '21 Nov 2020 23:59'          | System           | 13 Aug 2020 15:06:22 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 103' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:04', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:08', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System           | 25 Nov 2020 00:02:47 |



**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:12', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:16', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Chills](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Shortness of breath](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Difficulty breathing](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Fatigue](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |



US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Muscle aches](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Body aches](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[New loss of taste](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '0' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[New loss of smell](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '0' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Sore throat](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Congestion](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Runny nose](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '1' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |



US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Nausea](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '0' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '0' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                                                                                                                                                                                                                                                                           | User             | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                               | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:26', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '0' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                 | System           | 25 Nov 2020 00:02:47 |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:28', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:33', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System           | 25 Nov 2020 00:02:47 |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                              | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:35', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' | System           | 25 Nov 2020 00:02:47 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'                                                                                                                                                               | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-11-24T18:02:38', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '3c9e1fee-dc59-431b-8032-1a0f609946a2' User entered '24 Nov 2020 18:02:38' | System           | 25 Nov 2020 00:02:47 |
|                                                                                                                                                                                                                                                                                                    | System           | 25 Nov 2020 00:02:47 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 110' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Cough](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Shortness of breath](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Difficulty breathing](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Muscle aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Body aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Headache](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[New loss of taste](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[New loss of smell](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Sore throat](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Congestion](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Runny nose](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Nausea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Date and time of submission](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 117' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-12-07T12:00:19', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '63108850-4128-4281-8b90-c30f7be5012e' User entered 'No (N)' | System           | 07 Dec 2020 18:00:32 |
|                                                                                                                                                                                                                                                                                      | System           | 07 Dec 2020 18:00:32 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-12-07T12:00:21', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '63108850-4128-4281-8b90-c30f7be5012e' User entered 'No (N)' | System           | 07 Dec 2020 18:00:32 |
|                                                                                                                                                                                                                                                                                      | System           | 07 Dec 2020 18:00:32 |



US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-12-07T12:00:24', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: '63108850-4128-4281-8b90-c30f7be5012e' User entered '07 Dec 2020 12:00:24' | System           | 07 Dec 2020 18:00:32 |
|                                                                                                                                                                                                                                                                                                    | System           | 07 Dec 2020 18:00:32 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 124' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Shortness of breath](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Difficulty breathing](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

Fatigue

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Muscle aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Body aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Headache](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[New loss of taste](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[New loss of smell](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Sore throat](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Congestion](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Runny nose](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Nausea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Date and time of submission](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 131' | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[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) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-12-22T18:03:57', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f3943696-3845-4cfb-a4ad-2e8a0d38e083' | System           | 23 Dec 2020 00:04:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 23 Dec 2020 00:04:05 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-12-22T18:03:59', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f3943696-3845-4cfb-a4ad-2e8a0d38e083' | System           | 23 Dec 2020 00:04:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System           | 23 Dec 2020 00:04:05 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (559F56EF-6D7D-417D-AE30-4A84DBD99D4E)', Time: '2020-12-22T18:04:02', User OID: 'PatientReportedOutcome (US3342046)', ODM File OID: 'f3943696-3845-4cfb-a4ad-2e8a0d38e083' User entered '22 Dec 2020 18:04:02' | System           | 23 Dec 2020 00:04:05 |
|                                                                                                                                                                                                                                                                                                    | System           | 23 Dec 2020 00:04:05 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 138' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |



**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Chills](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Shortness of breath](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Difficulty breathing](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Muscle aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Body aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[New loss of taste](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[New loss of smell](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Sore throat](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Congestion](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Runny nose](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Nausea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Date and time of submission](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System           | 19 Nov 2020 05:48:17 |



US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|-------------------------------------------|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.     | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered 'Day 145' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

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) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

Have you been exposed to someone with 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) | 02 May 2021 14:05:09 |
|                   |                  |                      |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Shortness of breath](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Difficulty breathing](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Muscle aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Body aches](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[New loss of taste](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[New loss of smell](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Sore throat](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Congestion](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Runny nose](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |



US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

**US3342046**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Please 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)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder:** New Safety Follow Up Diary (1)

**Form:** Safety Follow Up Diary

**Generated On:** 11 Aug 2021 22:22:23

[Date and time of submission](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System           | 19 Nov 2020 05:48:17 |

US3342046

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:22:23**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User             | Time (GMT)           |
|-----------------------------------------------------|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| Amendment Manager: Data entry locked.               | System           | 19 Nov 2020 05:48:17 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System           | 19 Nov 2020 05:48:17 |

US3342046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 11 Nov 2020 17:32:49 |

US3342046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '11 Nov 2020' | Morgan Schulle (b) (4) | 11 Nov 2020 17:32:49 |

US3342046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded.                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Morgan Schulle (b) (4) | 11 Nov 2020 17:32:49 |



US3342046

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Morgan Schulle (b) (4) | 11 Nov 2020 17:32:49 |

US3342046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 27 Apr 2021 12:44:51 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | (b) (4)<br>Morgan Schulle (b) (4) | 11 Nov 2020 17:32:53 |

US3342046

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:44:51 |
| User entered '1'  | System           | 11 Nov 2020 17:32:53 |

US3342046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:45:27 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Dec 2020 18:08:15 |

US3342046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 29 Apr 2021 16:45:27 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered '23 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 23 Dec 2020 18:08:15 |

US3342046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 29 Apr 2021 16:45:27 |
| User signature succeeded.                  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Dec 2020 18:08:15 |

US3342046

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:22:23

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 16:45:27 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Dec 2020 18:08:15 |

US3342046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Is the participant continuing to the next visit?](#)

| Audit                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                        | (b) (4), (b) (6)                  | 29 Apr 2021 16:45:27 |
| User signature succeeded.                                | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User entered 'No (N)' reason for change: New Information | (b) (4)<br>Eileen Euperio (b) (4) | 14 Jan 2021 16:35:43 |
| User entered 'Yes (Y)'                                   | (b) (4)<br>(b) (4), (b) (6)       | 23 Dec 2020 18:08:19 |



US3342046

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:22:23

[Continuing Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 16:45:27 |
| User entered empty. | System           | 14 Jan 2021 16:35:43 |
| User entered '1'    | System           | 23 Dec 2020 18:08:19 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:23

[Date of Contact](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:11 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 21:49:06 |
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:44:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:23

[Time of Contact](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:11 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 21:49:06 |
| User entered '12:45'      | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:44:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:23

[Date and Time of Contact \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 17:40:11 |
| User entered '20 Nov 2020 12:45' | System           | 20 Nov 2020 19:44:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:23

[Type of Contact](#)

| Audit                                                                                                                                                                                                                                                                                                                           | User                    | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)        | 30 Apr 2021 17:40:11 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                       | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)        | 24 Nov 2020 22:15:01 |
| User closed query 'Source is unclear as to how site was initially contacted. If subject called site or was prompted to call site due to an eDiary entry, please select "safety call". Please clarify or update if needed.' (Site from CRA).                                                                                     | (b) (4), (b) (6)        | 24 Nov 2020 22:14:57 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                          | Eileen Euperio (b) (4)  | 24 Nov 2020 19:58:34 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' reason for change: Data Entry Error                                                                                                                                                                                                                          | (b) (4)                 |                      |
| Query 'Source is unclear as to how site was initially contacted. If subject called site or was prompted to call site due to an eDiary entry, please select "safety call". Please clarify or update if needed.' answered with 'updated AE source stating when subject had informed s via telephone of symptoms' (Site from CRA). | Eileen Euperio (b) (4)  | 24 Nov 2020 19:58:34 |
|                                                                                                                                                                                                                                                                                                                                 | (b) (4)                 |                      |
|                                                                                                                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)  | 24 Nov 2020 19:58:28 |
|                                                                                                                                                                                                                                                                                                                                 | (b) (4)                 |                      |
| User opened query 'Source is unclear as to how site was initially contacted. If subject called site or was prompted to call site due to an eDiary entry, please select "safety call". Please clarify or update if needed.' (Site from CRA).                                                                                     | (b) (4), (b) (6)        | 23 Nov 2020 22:00:49 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)        | 23 Nov 2020 21:49:06 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'                                                                                                                                                                                                                                                      | Darrell O'Brien (b) (4) | 20 Nov 2020 19:44:05 |
|                                                                                                                                                                                                                                                                                                                                 | (b) (4)                 |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:22:23

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:11 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 21:49:06 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:44:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                                           | User                    | Time (GMT)           |
|-------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                               | (b) (4), (b) (6)        | 30 Apr 2021 17:40:18 |
| User signature succeeded.                       | Paul Pickrell (b) (4)   | 22 Mar 2021 13:27:06 |
| User entered 'Day 4 (Day 4)' reason for change: | (b) (4)                 |                      |
| Data Entry Error                                | Eileen Euperio (b) (4)  | 24 Nov 2020 19:45:06 |
| User entered 'Day 1 (Day 1)'                    | (b) (4)                 |                      |
|                                                 | Darrell O'Brien (b) (4) | 20 Nov 2020 19:46:09 |
|                                                 | (b) (4)                 |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                                                                                                                                                                                                                                                      | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)        | 30 Apr 2021 17:40:18 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)   | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User closed query 'Date of Day 1 symptoms should be the same date as the AE date, which is not necessarily the same as the date of Illness Visit. Please clarify or update as needed.' (Site from CRA).                                                    | (b) (4), (b) (6)        | 24 Nov 2020 22:16:50 |
| Query 'Date of Day 1 symptoms should be the same date as the AE date, which is not necessarily the same as the date of Illness Visit. Please clarify or update as needed.' answered with 'added day 1,2, 3 lines, 20nov changed to day 4' (Site from CRA). | Eileen Euperio (b) (4)  | 24 Nov 2020 19:45:28 |
| User opened query 'Date of Day 1 symptoms should be the same date as the AE date, which is not necessarily the same as the date of Illness Visit. Please clarify or update as needed.' (Site from CRA).                                                    | (b) (4), (b) (6)        | 23 Nov 2020 20:18:50 |
| User entered '20 Nov 2020'                                                                                                                                                                                                                                 | Darrell O'Brien (b) (4) | 20 Nov 2020 19:46:09 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered '99'         | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered '99.4' F     | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                              | User                               | Time (GMT)           |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Moderate (Moderate)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                              | User                               | Time (GMT)           |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Moderate (Moderate)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                              | User                               | Time (GMT)           |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Moderate (Moderate)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Severe (Severe)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

Muscle Aches (Myalgia)

| Audit                                                                                                                                                                                                                                                                                               | User                               | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.                                                                                                                                                                                                                                                                           | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                 | (b) (4)<br>(b) (4), (b) (6)        | 18 Mar 2021 17:30:17 |
| User closed query 'Per CDM: Assessment information missing. Please consider adding missing data or if there is no data available then please consider selecting "Not Done". ' (Site from DM).                                                                                                       | (b) (4), (b) (6)                   | 16 Mar 2021 08:43:33 |
| Query 'Per CDM: Assessment information missing. Please consider adding missing data or if there is no data available then please consider selecting "Not Done". ' answered with 'EDC updated to reflect source. Muscle aches was not an ongoing sx during Illness Visit D1 (Day 4)' (Site from DM). | Ethan Shotton (b) (4)<br>(b) (4)   | 15 Mar 2021 17:48:49 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                              | Ethan Shotton (b) (4)<br>(b) (4)   | 15 Mar 2021 17:47:46 |
| User entered 'None (None)' reason for change: Data Entry Error                                                                                                                                                                                                                                      | Ethan Shotton (b) (4)<br>(b) (4)   | 15 Mar 2021 17:47:46 |
| User opened query 'Per CDM: Assessment information missing. Please consider adding missing data or if there is no data available then please consider selecting "Not Done". ' (Site from DM).                                                                                                       | (b) (4), (b) (6)                   | 05 Feb 2021 13:46:35 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                   | 24 Nov 2020 22:16:55 |
| User entered empty.                                                                                                                                                                                                                                                                                 | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                              | User                               | Time (GMT)           |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Moderate (Moderate)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                              | User                               | Time (GMT)           |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Moderate (Moderate)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:46:09 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                                           | User                   | Time (GMT)           |
|-------------------------------------------------|------------------------|----------------------|
| Data hard locked.                               | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| User signature succeeded.                       | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'Day 5 (Day 5)' reason for change: | (b) (4)                |                      |
| Data Entry Error                                | Eileen Euperio (b) (4) | 24 Nov 2020 19:45:06 |
| User entered 'Day 2 (Day 2)'                    | (b) (4)                |                      |
|                                                 | Stefanie Mott (b) (4)  | 22 Nov 2020 23:06:10 |
|                                                 |                        |                      |
|                                                 |                        |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '21 Nov 2020' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '0'          | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '93'         | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '98.1' F     | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Moderate (Moderate)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                                                          | User                        | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                                            | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:48 |
| User entered 'None (None)'                                     | Stefanie Mott (b) (4)       | 22 Nov 2020 23:06:10 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                                           | User                   | Time (GMT)           |
|-------------------------------------------------|------------------------|----------------------|
| Data hard locked.                               | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| User signature succeeded.                       | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'Day 6 (Day 6)' reason for change: | (b) (4)                |                      |
| Data Entry Error                                | Eileen Euperio (b) (4) | 24 Nov 2020 19:45:06 |
| User entered 'Day 3 (Day 3)'                    | (b) (4)                |                      |
|                                                 | Stefanie Mott (b) (4)  | 22 Nov 2020 23:08:18 |
|                                                 |                        |                      |
|                                                 |                        |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '22 Nov 2020' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '0'          | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '95'         | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '97.1' F     | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 22 Nov 2020 23:08:18 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                                           | User                   | Time (GMT)           |
|-------------------------------------------------|------------------------|----------------------|
| Data hard locked.                               | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| User signature succeeded.                       | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'Day 7 (Day 7)' reason for change: | (b) (4)                |                      |
| Data Entry Error                                | Eileen Euperio (b) (4) | 24 Nov 2020 19:45:06 |
| User entered 'Day 4 (Day 4)'                    | (b) (4)                |                      |
|                                                 | Stefanie Mott (b) (4)  | 23 Nov 2020 23:20:31 |
|                                                 |                        |                      |
|                                                 |                        |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '23 Nov 2020' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '0'          | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '97'         | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered '97.5' F     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:16:55 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 23 Nov 2020 23:20:31 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                        | User                   | Time (GMT)           |
|------------------------------|------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| User signature succeeded.    | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'Day 1 (Day 1)' | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered '17 Nov 2020' | Eileen Euperio (b) (4)<br>(b) (4) | 24 Nov 2020 19:44:19 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                                                                                                                                                                                                                                    | User                                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                        | (b) (4), (b) (6)                     | 30 Apr 2021 17:40:18 |
| User signature succeeded.                                                                                                                                                                                                                | Paul Pickrell (b) (4)                | 12 Apr 2021 15:26:51 |
| DataPoint Verified.                                                                                                                                                                                                                      | (b) (4)<br>(b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User closed query 'Source includes symptoms for D1-D3 (17-19NOV2020) but does not include intensity of symptoms. Please review and clarify symptoms listed in source and update EDC. ' (Site from CRA).                                  | (b) (4), (b) (6)                     | 31 Mar 2021 18:24:52 |
| Signature has been broken.                                                                                                                                                                                                               | Ethan Shotton (b) (4)                | 30 Mar 2021 21:55:19 |
| User entered '0' reason for change: Data Entry Error                                                                                                                                                                                     | (b) (4)<br>Ethan Shotton (b) (4)     | 30 Mar 2021 21:55:19 |
| User signature succeeded.                                                                                                                                                                                                                | (b) (4)<br>Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| Query 'Source includes symptoms for D1-D3 (17-19NOV2020) but does not include intensity of symptoms. Please review and clarify symptoms listed in source and update EDC. ' answered with 'intensity included in source' (Site from CRA). | Olivia Hapanowicz (b) (4)<br>(b) (4) | 19 Mar 2021 13:51:56 |
| User opened query 'Source includes symptoms for D1-D3 (17-19NOV2020) but does not include intensity of symptoms. Please review and clarify symptoms listed in source and update EDC. ' (Site from CRA).                                  | (b) (4), (b) (6)                     | 18 Mar 2021 18:03:44 |
| DataPoint Un-verified.                                                                                                                                                                                                                   | (b) (4), (b) (6)                     | 18 Mar 2021 17:34:34 |
| DataPoint Verified.                                                                                                                                                                                                                      | (b) (4), (b) (6)                     | 24 Nov 2020 22:16:55 |
| User entered '1'                                                                                                                                                                                                                         | Eileen Euperio (b) (4)<br>(b) (4)    | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                                      | (b) (4), (b) (6)       | 18 Mar 2021 17:34:36 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                                         | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'    | System           | 19 Mar 2021 13:51:39 |
| User entered empty. | System           | 24 Nov 2020 19:44:19 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                                      | (b) (4), (b) (6)       | 18 Mar 2021 17:34:37 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                                         | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:39 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:51:39 |
|                                                                | (b) (4), (b) (6)          | 18 Mar 2021 17:34:41 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                   |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:43 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:44 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                                             | User                      | Time (GMT)           |
|---------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                               | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                         | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Severe (Severe)' reason for change: | (b) (4)                   |                      |
| Data Entry Error                                  | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                            | (b) (4), (b) (6)          | 18 Mar 2021 17:34:47 |
| DataPoint Verified.                               | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                               | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:19 |
|                                                   | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:50 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:52 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:54 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:57 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:34:59 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:51:39 |
|                                                                | (b) (4), (b) (6)          | 18 Mar 2021 17:35:01 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:51:39 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 18 Mar 2021 17:35:03 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | (b) (4), (b) (6)          |                      |
|                                                                | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                   |                      |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:05 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:06 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:09 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:51:39 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:10 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:19 |
|                                                                | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                        | User                   | Time (GMT)           |
|------------------------------|------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| User signature succeeded.    | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'Day 2 (Day 2)' | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered '18 Nov 2020' | Eileen Euperio (b) (4)<br>(b) (4) | 24 Nov 2020 19:44:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                                                | User                              | Time (GMT)           |
|------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:18 |
| User signature succeeded.                            | Paul Pickrell (b) (4)             | 12 Apr 2021 15:26:51 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| Signature has been broken.                           | Ethan Shotton (b) (4)             | 30 Mar 2021 21:55:19 |
| User entered '0' reason for change: Data Entry Error | (b) (4)<br>Ethan Shotton (b) (4)  | 30 Mar 2021 21:55:19 |
| User signature succeeded.                            | (b) (4)<br>Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| DataPoint Un-verified.                               | (b) (4)<br>(b) (4), (b) (6)       | 18 Mar 2021 17:35:24 |
| DataPoint Verified.                                  | (b) (4), (b) (6)                  | 24 Nov 2020 22:16:55 |
| User entered '1'                                     | Eileen Euperio (b) (4)<br>(b) (4) | 24 Nov 2020 19:44:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                                      | (b) (4), (b) (6)       | 18 Mar 2021 17:35:26 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                                         | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'    | System           | 19 Mar 2021 13:54:25 |
| User entered empty. | System           | 24 Nov 2020 19:44:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                                      | (b) (4), (b) (6)       | 18 Mar 2021 17:35:28 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                                         | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:30 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:54:25 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 18 Mar 2021 17:35:32 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | (b) (4), (b) (6)          |                      |
|                                                                | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                   |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:34 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:36 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                                             | User                      | Time (GMT)           |
|---------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                               | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                         | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Severe (Severe)' reason for change: | (b) (4)                   |                      |
| Data Entry Error                                  | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                            | (b) (4), (b) (6)          | 18 Mar 2021 17:35:37 |
| DataPoint Verified.                               | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                               | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:27 |
|                                                   | (b) (4)                   |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:35:39 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:02 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:04 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:06 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:07 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:54:25 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 18 Mar 2021 17:41:09 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | (b) (4), (b) (6)          |                      |
|                                                                | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)          | 18 Mar 2021 17:41:11 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                   |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)          | 18 Mar 2021 17:41:12 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                   |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:23 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:24 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:54:25 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:41:28 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:27 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                        | User                   | Time (GMT)           |
|------------------------------|------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| User signature succeeded.    | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'Day 3 (Day 3)' | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| DataPoint Un-verified.     | (b) (4), (b) (6)       | 18 Mar 2021 17:43:30 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered '19 Nov 2020' | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                                                | User                              | Time (GMT)           |
|------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:18 |
| User signature succeeded.                            | Paul Pickrell (b) (4)             | 12 Apr 2021 15:26:51 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| Signature has been broken.                           | Ethan Shotton (b) (4)             | 30 Mar 2021 21:55:19 |
| User entered '0' reason for change: Data Entry Error | (b) (4)<br>Ethan Shotton (b) (4)  | 30 Mar 2021 21:55:19 |
| User signature succeeded.                            | (b) (4)<br>Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| DataPoint Un-verified.                               | (b) (4)<br>(b) (4), (b) (6)       | 18 Mar 2021 17:43:32 |
| DataPoint Verified.                                  | (b) (4), (b) (6)                  | 24 Nov 2020 22:16:55 |
| User entered '1'                                     | Eileen Euperio (b) (4)<br>(b) (4) | 24 Nov 2020 19:44:37 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | (b) (4)              |
| DataPoint Un-verified.                                                      | (b) (4), (b) (6)       | 18 Mar 2021 17:55:46 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                                         | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                             | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'    | System           | 19 Mar 2021 13:56:26 |
| User entered empty. | System           | 24 Nov 2020 19:44:37 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                                                                       | User                   | Time (GMT)           |
|-----------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                           | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                                   | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)                | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                                      | (b) (4), (b) (6)       | 18 Mar 2021 17:55:48 |
| DataPoint Verified.                                                         | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                                         | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                             | (b) (4)                |                      |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                                 | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                        | (b) (4), (b) (6)          | 18 Mar 2021 17:55:50 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                                    | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                        | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                | (b) (4), (b) (6)          | 18 Mar 2021 17:55:51 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                                 | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                        | (b) (4), (b) (6)          | 18 Mar 2021 17:55:53 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                                    | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                        | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                                 | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                        | (b) (4), (b) (6)          | 18 Mar 2021 17:55:55 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                                    | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                        | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                                             | User                      | Time (GMT)           |
|---------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                               | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                         | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Severe (Severe)' reason for change: | (b) (4)                   |                      |
| Data Entry Error                                  | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                            | (b) (4), (b) (6)          | 18 Mar 2021 17:55:57 |
| DataPoint Verified.                               | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                               | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                   | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 19 Mar 2021 13:56:26 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 18 Mar 2021 17:55:59 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 22:16:55 |
|                                                                | (b) (4)                | 24 Nov 2020 19:44:37 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                                 | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                        | (b) (4), (b) (6)          | 18 Mar 2021 17:56:01 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                                    | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                        | (b) (4)                   |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                                                                  | User                      | Time (GMT)           |
|------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                                 | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                        | (b) (4), (b) (6)          | 18 Mar 2021 17:56:03 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                                    | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                        | (b) (4)                   |                      |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:56:05 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:56:06 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                |                      |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                | (b) (4), (b) (6)          |                      |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 18 Mar 2021 17:56:08 |
|                                                                | (b) (4), (b) (6)          |                      |
| User entered empty.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
|                                                                | Eileen Euperio (b) (4)    |                      |
|                                                                | (b) (4)                   | 24 Nov 2020 19:44:37 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
|                                                                | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)          | 18 Mar 2021 17:56:10 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                   |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | (b) (4)              |
| Olivia Hapanowicz                                              | (b) (4)                | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:56:11 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:56:13 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)       | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)  | 22 Mar 2021 13:27:06 |
| User entered 'None (None)' reason for change: Data Entry Error | (b) (4)                | 19 Mar 2021 13:56:26 |
| DataPoint Un-verified.                                         | (b) (4), (b) (6)       | 18 Mar 2021 17:56:15 |
| DataPoint Verified.                                            | (b) (4), (b) (6)       | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4) | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                |                      |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                                                          | User                      | Time (GMT)           |
|----------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)          | 30 Apr 2021 17:40:18 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 31 Mar 2021 18:28:28 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)     | 22 Mar 2021 13:27:06 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4)                   |                      |
| DataPoint Un-verified.                                         | Olivia Hapanowicz (b) (4) | 19 Mar 2021 13:56:26 |
|                                                                | (b) (4), (b) (6)          | 18 Mar 2021 17:56:17 |
| DataPoint Verified.                                            | (b) (4), (b) (6)          | 24 Nov 2020 22:16:55 |
| User entered empty.                                            | Eileen Euperio (b) (4)    | 24 Nov 2020 19:44:37 |
|                                                                | (b) (4)                   |                      |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.    | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 8 (Day 8)' | (b) (4)<br>Stefanie Mott (b) (4) | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered '24 Nov 2020' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered '0'          | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered '97'         | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered '97.0' F     | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:48 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:55:53 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.    | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 9 (Day 9)' | (b) (4)<br>Stefanie Mott (b) (4) | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered '25 Nov 2020' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered '0'          | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered '96'         | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered '97.8' F     | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.          | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'Moderate (Moderate)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:53 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:43:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 10 (Day 10)' | (b) (4)<br>Stefanie Mott (b) (4) | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered '26 Nov 2020' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered '0'          | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered '97'         | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 30 Nov 2020 14:44:19 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered '97.6' F     | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'Mild (Mild)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:23:58 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:44:19 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 11 (Day 11)' | (b) (4)<br>Stefanie Mott (b) (4) | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered '27 Nov 2020' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered '0'          | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered '98'         | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 30 Nov 2020 14:46:44 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered '97.1' F     | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:30 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:46:44 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 12 (Day 12)' | (b) (4)<br>Stefanie Mott (b) (4) | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered '28 Nov 2020' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered '0'          | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered '98'         | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered '97.5' F     | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:31 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:50:41 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 13 (Day 13)' | (b) (4)<br>Stefanie Mott (b) (4) | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered '29 Nov 2020' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered '0'          | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered '98'         | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered '97.6' F     | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:34 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 30 Nov 2020 14:52:14 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 14 (Day 14)' | (b) (4)<br>Stefanie Mott (b) (4) | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered '30 Nov 2020' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered '0'          | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered '99'         | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered '97.7' F     | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:38 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 00:00:27 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 15 (Day 15)' | (b) (4)<br>Stefanie Mott (b) (4) | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered '1 Dec 2020' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered '0'          | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered '99'         | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered '98.2' F     | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:41 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 01 Dec 2020 23:47:05 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 16 (Day 16)' | (b) (4)<br>Stefanie Mott (b) (4) | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered '2 Dec 2020' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered '0'          | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered '99'         | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered '98.2' F     | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:43 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 02 Dec 2020 22:03:52 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 17 (Day 17)' | (b) (4)<br>Stefanie Mott (b) (4) | 04 Dec 2020 23:35:32 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered '3 Dec 2020' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered '1'          | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered empty. | System           | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:45 |
| User entered empty.       | Stefanie Mott (b) (4)       | 04 Dec 2020 23:35:32 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Symptom Day](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 30 Apr 2021 17:40:18 |
| User signature succeeded.      | Paul Pickrell (b) (4)            | 22 Mar 2021 13:27:06 |
| User entered 'Day 18 (Day 18)' | (b) (4)<br>Stefanie Mott (b) (4) | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered '4 Dec 2020' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Assessment Not Done](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered '0'          | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered '99'         | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:18 |
| User entered '%'  | System           | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Temperature](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered '98.3' F     | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Chills](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Cough](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Shortness of Breath](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Difficulty Breathing](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Fatigue](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Body Aches](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Headache](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Taste](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[New Loss of Smell](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Nasal Congestion](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Nausea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Vomiting](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |



US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Diarrhea](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:22:23

[Sore Throat](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:18 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 22 Mar 2021 13:27:06 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Mar 2021 18:32:47 |
| User entered 'None (None)' | Stefanie Mott (b) (4)       | 04 Dec 2020 23:36:54 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[Date of Visit](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered '20 Nov 2020' | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[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 17:40:24 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered 'Yes (Y)'    | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[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 17:40:24 |
| User signature succeeded.                                                                                                                                                                                                                                    | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).                                                          | (b) (4), (b) (6)      | 04 Dec 2020 18:26:47 |
| DataPoint Verified.                                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 23 Nov 2020 20:31:01 |
| 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 'confirmed positive diagnosis and recorded on AE form' (Site from System). | Stefanie Mott (b) (4) | 23 Nov 2020 18:31:31 |
| 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                | 23 Nov 2020 18:30:59 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                       | Stefanie Mott (b) (4) | 23 Nov 2020 18:30:59 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[Date of Test](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 17:40:24 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered '20 Nov 2020' | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[Type of Test Performed](#)

| Audit                                                    | User                        | Time (GMT)           |
|----------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                        | (b) (4), (b) (6)            | 30 Apr 2021 17:40:24 |
| User signature succeeded.                                | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                      | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:24 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[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 17:40:24 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[Lab/ Institution Test Performed](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:24 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[CLIA Certified?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:24 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 20:31:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:30:59 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:22:23

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:40:24 |
| User entered '1'  | System           | 23 Nov 2020 18:30:59 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[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 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

| Audit                                                                                                                | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked.                                                                                                    | (b) (4), (b) (6)       | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                                                            | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                  | (b) (4), (b) (6)       | 02 Feb 2021 16:37:45 |
| User closed query 'Please revisit response as an O2 sat of 93% is noted on 21Nov2020. ' (Site from CRA).             | (b) (4), (b) (6)       | 02 Feb 2021 16:36:23 |
| Query 'Please revisit response as an O2 sat of 93% is noted on 21Nov2020. ' answered with 'UPDATED' (Site from CRA). | Eileen Euperio (b) (4) | 01 Feb 2021 20:58:27 |
| DataPoint Un-verified.                                                                                               | (b) (4)                | 01 Feb 2021 20:58:19 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                           | Eileen Euperio (b) (4) | 01 Feb 2021 20:58:19 |
| User opened query 'Please revisit response as an O2 sat of 93% is noted on 21Nov2020. ' (Site from CRA).             | (b) (4), (b) (6)       | 26 Jan 2021 21:53:19 |
| DataPoint Verified.                                                                                                  | (b) (4), (b) (6)       | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'                                                                                                | Stefanie Mott (b) (4)  | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                            | (b) (4)<br>(b) (4), (b) (6)       | 02 Feb 2021 16:37:45 |
| DataPoint Un-verified.                                         | Eileen Euperio (b) (4)            | 01 Feb 2021 20:58:19 |
| User entered '21 Nov 2020' reason for change: Data Entry Error | (b) (4)<br>Eileen Euperio (b) (4) | 01 Feb 2021 20:58:19 |
| DataPoint Verified.                                            | (b) (4), (b) (6)                  | 24 Nov 2020 22:07:01 |
| User entered empty.                                            | Stefanie Mott (b) (4)             | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                            | (b) (4)<br>(b) (4), (b) (6)       | 02 Feb 2021 16:37:45 |
| DataPoint Un-verified.                                         | Eileen Euperio (b) (4)            | 01 Feb 2021 20:58:19 |
| User entered '21 Nov 2020' reason for change: Data Entry Error | (b) (4)<br>Eileen Euperio (b) (4) | 01 Feb 2021 20:58:19 |
| DataPoint Verified.                                            | (b) (4), (b) (6)                  | 24 Nov 2020 22:07:01 |
| User entered empty.                                            | Stefanie Mott (b) (4)             | 23 Nov 2020 23:21:33 |

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Oxygen Saturation](#)

| Audit                                                 | User                              | Time (GMT)           |
|-------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:31 |
| User signature succeeded.                             | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6)       | 02 Feb 2021 16:37:45 |
| DataPoint Un-verified.                                | Eileen Euperio (b) (4)            | 01 Feb 2021 20:58:19 |
| User entered '93' reason for change: Data Entry Error | (b) (4)<br>Eileen Euperio (b) (4) | 01 Feb 2021 20:58:19 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6)       | 24 Nov 2020 22:07:01 |
| User entered empty.                                   | Stefanie Mott (b) (4)             | 23 Nov 2020 23:21:33 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Form: Covid-19 Severity Assessment

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[PaO2](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Did the subject have Respiratory failure?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 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 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Form: Covid-19 Severity Assessment

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit                                                                                  | User                        | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                    | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                      | 23 Nov 2020 23:21:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                      | 23 Nov 2020 23:21:46 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:46 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                      | 23 Nov 2020 23:21:33 |
| User entered empty.                                                                    | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 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 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |



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[High-Flow Oxygen?](#)

| Audit                                                                                                                                                                                                                   | User                        | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                       | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                                                                                                                                                               | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User closed query 'Based on eCRF guidelines (v.4), this should be left blank, as the above 2 questions were answered "no". Please clarify or update as necessary.' (Site from CRA).                                     | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 19:50:22 |
| DataPoint Verified.                                                                                                                                                                                                     | (b) (4), (b) (6)            | 04 Mar 2021 19:50:20 |
| Query 'Based on eCRF guidelines (v.4), this should be left blank, as the above 2 questions were answered "no". Please clarify or update as necessary.' answered with 'edc updated per eCRF guidelines' (Site from CRA). | Stefanie Mott (b) (4)       | 25 Feb 2021 17:22:51 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                  | Stefanie Mott (b) (4)       | 25 Feb 2021 17:22:33 |
| User opened query 'Based on eCRF guidelines (v.4), this should be left blank, as the above 2 questions were answered "no". Please clarify or update as necessary.' (Site from CRA).                                     | (b) (4), (b) (6)            | 03 Feb 2021 15:20:51 |
| DataPoint Un-verified.                                                                                                                                                                                                  | (b) (4), (b) (6)            | 03 Feb 2021 15:18:17 |
| DataPoint Verified.                                                                                                                                                                                                     | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'                                                                                                                                                                                                   | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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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 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Non-Invasive Ventilation?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 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 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[ECMO?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit                                                                                                                                                                                       | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                           | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                                                                                                                                   | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.<br>' (Site from DM).                                                     | (b) (4)<br>(b) (4), (b) (6)       | 19 Jan 2021 12:57:40 |
| Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.<br>' answered with 'no changes to severity assessment were reported' (Site from DM). | Eileen Euperio (b) (4)<br>(b) (4) | 14 Jan 2021 16:35:16 |
| User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia and update accordingly.<br>' (Site from DM).                                                     | (b) (4), (b) (6)                  | 04 Jan 2021 20:43:39 |
| DataPoint Verified.                                                                                                                                                                         | (b) (4), (b) (6)                  | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'                                                                                                                                                                       | Stefanie Mott (b) (4)             | 23 Nov 2020 23:21:33 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Evidence of Shock Requires  
Vasopressors](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Acute Renal Dysfunction?](#)

| Audit                                                                                                | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                    | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                                            | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 20:38:39 |
| User closed query 'Source indicates "no". Please update as necessary.' (Site from CRA).              | (b) (4), (b) (6)            | 04 Mar 2021 20:38:37 |
| Query 'Source indicates "no". Please update as necessary.' answered with 'updated ' (Site from CRA). | Stefanie Mott (b) (4)       | 25 Feb 2021 17:23:18 |
| User entered 'No (N)' reason for change: Data Entry Error                                            | Stefanie Mott (b) (4)       | 25 Feb 2021 17:22:33 |
| User opened query 'Source indicates "no". Please update as necessary.' (Site from CRA).              | (b) (4), (b) (6)            | 03 Feb 2021 15:28:29 |
| DataPoint Un-verified.                                                                               | (b) (4), (b) (6)            | 03 Feb 2021 15:27:43 |
| DataPoint Verified.                                                                                  | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered empty.                                                                                  | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 19:55:18 |
| DataPoint Un-verified.    | (b) (4), (b) (6)            | 03 Feb 2021 15:27:46 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Hepatic Dysfunction?](#)

| Audit                                                                                                | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                    | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                                            | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User closed query 'Source indicates "no". Please update as necessary.' (Site from CRA).              | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 20:38:43 |
| DataPoint Verified.                                                                                  | (b) (4), (b) (6)            | 04 Mar 2021 20:38:41 |
| Query 'Source indicates "no". Please update as necessary.' answered with 'updated ' (Site from CRA). | Stefanie Mott (b) (4)       | 25 Feb 2021 17:23:27 |
| User entered 'No (N)' reason for change: Data Entry Error                                            | Stefanie Mott (b) (4)       | 25 Feb 2021 17:22:33 |
| User opened query 'Source indicates "no". Please update as necessary.' (Site from CRA).              | (b) (4), (b) (6)            | 03 Feb 2021 15:28:41 |
| DataPoint Un-verified.                                                                               | (b) (4), (b) (6)            | 03 Feb 2021 15:27:50 |
| DataPoint Verified.                                                                                  | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered empty.                                                                                  | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 19:55:16 |
| DataPoint Un-verified.    | (b) (4), (b) (6)            | 03 Feb 2021 15:27:52 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

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[Neurologic Dysfunction?](#)

| Audit                                                                                                | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                    | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded.                                                                            | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User closed query 'Source indicates "no". Please update as necessary.' (Site from CRA).              | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 20:38:46 |
| DataPoint Verified.                                                                                  | (b) (4), (b) (6)            | 04 Mar 2021 20:38:45 |
| Query 'Source indicates "no". Please update as necessary.' answered with 'updated ' (Site from CRA). | Stefanie Mott (b) (4)       | 25 Feb 2021 17:23:34 |
| User entered 'No (N)' reason for change: Data Entry Error                                            | Stefanie Mott (b) (4)       | 25 Feb 2021 17:22:33 |
| User opened query 'Source indicates "no". Please update as necessary.' (Site from CRA).              | (b) (4), (b) (6)            | 03 Feb 2021 15:28:53 |
| DataPoint Un-verified.                                                                               | (b) (4), (b) (6)            | 03 Feb 2021 15:27:54 |
| DataPoint Verified.                                                                                  | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered empty.                                                                                  | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 19:55:14 |
| DataPoint Un-verified.    | (b) (4), (b) (6)            | 03 Feb 2021 15:27:57 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |



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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Clinical Evidence](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Date of Assessment](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Radiographical Evidence](#)

| Audit                                                  | User                        | Time (GMT)           |
|--------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded.                              | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                    | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty; reason for change Data Entry Error | Stefanie Mott (b) (4)       | 23 Nov 2020 23:22:06 |
| User entered 'No (N)'                                  | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Date of Assessment](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[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 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[Start Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

US3342046

Folder: Covid-19 Assessment 20 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:22:23

[End Date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:40:31 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 22:07:01 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 23:21:33 |

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Folder: Covid-19 Assessment 20 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:22:23

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 30 Apr 2021 17:40:47 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 02 Feb 2021 16:38:01 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 14 Jan 2021 16:35:29 |



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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                       | User                  | Time (GMT)           |
|---------------------------------------------|-----------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User accepted default value 'Day 3 (Day 3)' | Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:22:23

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)'    | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered '22 Nov 2020' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                       | User                  | Time (GMT)           |
|---------------------------------------------|-----------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User accepted default value 'Day 5 (Day 5)' | Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:22:23

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)'    | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered '24 Nov 2020' | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                                                                                      | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                          | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User closed query 'Per ETRTR, Please enter data for Day 7, Day 9 and Day 14.' (Site from CRA).             | (b) (4), (b) (6)        | 02 Feb 2021 18:20:14 |
| Query 'Per ETRTR, Please enter data for Day 7, Day 9 and Day 14.' answered with 'Updated' (Site from CRA). | Darrell O'Brien (b) (4) | 17 Dec 2020 21:36:14 |
| User opened query 'Per ETRTR, Please enter data for Day 7, Day 9 and Day 14.' (Site from CRA).             | (b) (4), (b) (6)        | 09 Dec 2020 22:12:50 |
| User accepted default value 'Day 7 (Day 7)'                                                                | Stefanie Mott (b) (4)   | 25 Nov 2020 14:56:40 |

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

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[Was Saliva Collected?](#)

| Audit                                                                                                            | User                        | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                                | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                        | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                              | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)' reason for change: New Information                                                        | Darrell O'Brien (b) (4)     | 17 Dec 2020 21:36:05 |
| User closed query 'Data is required. Please complete.' (Site from System).                                       | (b) (4), (b) (6)            | 26 Nov 2020 08:21:35 |
| Query 'Data is required. Please complete.' answered with 'WILL ENTER WHEN DATA IS AVAILABLE' (Site from System). | Stefanie Mott (b) (4)       | 25 Nov 2020 18:05:51 |
| User opened query 'Data is required. Please complete.' (Site from System).                                       | System                      | 25 Nov 2020 14:56:40 |
| User entered empty.                                                                                              | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |



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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                                                                                                                                                                                                                                                                                                                                             | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                         | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                               | (b) (4)<br>(b) (4), (b) (6)        | 02 Feb 2021 18:20:28 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26,28NOV2020 and 03DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' (Site from DM).             | (b) (4), (b) (6)                   | 18 Dec 2020 19:45:11 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26,28NOV2020 and 03DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' answered with 'Updated' (Site from DM). | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:36:19 |
| User entered '26 Nov 2020' reason for change: New Information                                                                                                                                                                                                                                                                                     | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:36:05 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26,28NOV2020 and 03DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.<br>' (Site from DM).             | (b) (4), (b) (6)                   | 10 Dec 2020 05:08:18 |
| User entered empty.                                                                                                                                                                                                                                                                                                                               | Stefanie Mott (b) (4)              | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                       | User                  | Time (GMT)           |
|---------------------------------------------|-----------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User accepted default value 'Day 9 (Day 9)' | Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:22:23

[Was Saliva Collected?](#)

| Audit                                                                                                           | User                        | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                               | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                       | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                             | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)' reason for change: New Information                                                       | Darrell O'Brien (b) (4)     | 17 Dec 2020 21:35:45 |
| User closed query 'Data is required. Please complete.' (Site from System).                                      | (b) (4), (b) (6)            | 26 Nov 2020 08:21:40 |
| Query 'Data is required. Please complete.' answered with 'WILL ENTER WHEN DATA IS OBTAINED' (Site from System). | Stefanie Mott (b) (4)       | 25 Nov 2020 18:06:10 |
| User opened query 'Data is required. Please complete.' (Site from System).                                      | System                      | 25 Nov 2020 14:56:40 |
| User entered empty.                                                                                             | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                                                         | User                               | Time (GMT)           |
|---------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                             | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                     | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                           | (b) (4)<br>(b) (4), (b) (6)        | 02 Feb 2021 18:20:28 |
| User entered '28 Nov 2020' reason for change: New Information | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:35:45 |
| User entered empty.                                           | Stefanie Mott (b) (4)              | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                                                                                                                                                                                                                                                                                                                             | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| 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.<br>' (Site from DM).                 | (b) (4), (b) (6)                  | 19 Jan 2021 08:51:38 |
| 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.<br>' answered with 'updated crf' (Site from DM). | Eileen Euperio (b) (4)<br>(b) (4) | 14 Jan 2021 16:34:24 |
| 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.<br>' (Site from DM).                 | (b) (4), (b) (6)                  | 24 Dec 2020 08:25:06 |
| User accepted default value 'Day 14 (Day 14)'                                                                                                                                                                                                                                                                                                     | Stefanie Mott (b) (4)             | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:22:23

[Was Saliva Collected?](#)

| Audit                                                                                                           | User                        | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                               | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                       | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                             | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)' reason for change: New Information                                                       | Darrell O'Brien (b) (4)     | 17 Dec 2020 21:35:13 |
| User closed query 'Data is required. Please complete.' (Site from System).                                      | (b) (4), (b) (6)            | 26 Nov 2020 08:21:46 |
| Query 'Data is required. Please complete.' answered with 'WILL ENTER WHEN DATA IS OBTAINED' (Site from System). | Stefanie Mott (b) (4)       | 25 Nov 2020 18:06:20 |
| User opened query 'Data is required. Please complete.' (Site from System).                                      | System                      | 25 Nov 2020 14:56:40 |
| User entered empty.                                                                                             | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                                                                                                                                                                                                                                                                                                                              | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                          | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                | (b) (4)<br>(b) (4), (b) (6)        | 02 Feb 2021 18:20:28 |
| User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 10DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).                 | (b) (4), (b) (6)                   | 19 Jan 2021 08:51:36 |
| Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 10DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated crf' (Site from DM). | Eileen Euperio (b) (4)<br>(b) (4)  | 14 Jan 2021 16:34:29 |
| User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 10DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).                 | (b) (4), (b) (6)                   | 24 Dec 2020 08:24:58 |
| User entered '03 Dec 2020' reason for change: New Information                                                                                                                                                                                                                                                                      | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:35:13 |
| User entered empty.                                                                                                                                                                                                                                                                                                                | Stefanie Mott (b) (4)              | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                         | User                  | Time (GMT)           |
|-----------------------------------------------|-----------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User accepted default value 'Day 21 (Day 21)' | Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |



US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:22:23

[Was Saliva Collected?](#)

| Audit                                                                                                           | User                        | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                               | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                       | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                             | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                      | Eileen Euperio (b) (4)      | 14 Jan 2021 16:32:35 |
| User closed query 'Data is required. Please complete.' (Site from System).                                      | (b) (4)<br>(b) (4), (b) (6) | 26 Nov 2020 08:21:52 |
| Query 'Data is required. Please complete.' answered with 'WILL ENTER WHEN DATA IS OBTAINED' (Site from System). | Stefanie Mott (b) (4)       | 25 Nov 2020 18:06:29 |
| User opened query 'Data is required. Please complete.' (Site from System).                                      | System                      | 25 Nov 2020 14:56:40 |
| User entered empty.                                                                                             | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                                                          | User                             | Time (GMT)           |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                 | 02 May 2021 14:05:09 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                            | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 18:20:28 |
| User entered '10 Dec 2020' reason for change: Data Entry Error | Eileen Euperio (b) (4)           | 14 Jan 2021 16:32:35 |
| User entered empty.                                            | (b) (4)<br>Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:22:23

[Visit](#)

| Audit                                         | User                  | Time (GMT)           |
|-----------------------------------------------|-----------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User accepted default value 'Day 28 (Day 28)' | Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:22:23

[Was Saliva Collected?](#)

| Audit                                                                                                           | User                        | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                               | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                       | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                             | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 18:20:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                      | Eileen Euperio (b) (4)      | 14 Jan 2021 16:34:08 |
| User closed query 'Data is required. Please complete.' (Site from System).                                      | (b) (4)<br>(b) (4), (b) (6) | 26 Nov 2020 08:21:57 |
| Query 'Data is required. Please complete.' answered with 'WILL ENTER WHEN DATA IS OBTAINED' (Site from System). | Stefanie Mott (b) (4)       | 25 Nov 2020 18:06:42 |
| User opened query 'Data is required. Please complete.' (Site from System).                                      | System                      | 25 Nov 2020 14:56:40 |
| User entered empty.                                                                                             | Stefanie Mott (b) (4)       | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                                                          | User                             | Time (GMT)           |
|----------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                 | 02 May 2021 14:05:09 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                            | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 18:20:28 |
| User entered '17 Dec 2020' reason for change: Data Entry Error | Eileen Euperio (b) (4)           | 14 Jan 2021 16:34:08 |
| User entered empty.                                            | (b) (4)<br>Stefanie Mott (b) (4) | 25 Nov 2020 14:56:40 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Was this visit performed?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                      | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| User closed query 'Please complete Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection page as expected.' (Site from CRA).                                                                                                                                                                                                                                          | (b) (4)<br>(b) (4), (b) (6)        | 02 Feb 2021 16:39:39 |
| Query 'Please complete Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection page as expected.' answered with 'Updated' (Site from CRA).                                                                                                                                                                                                                              | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:37:34 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).    | (b) (4), (b) (6)                   | 10 Dec 2020 07:04:08 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6)                   | 10 Dec 2020 07:03:15 |
| User opened query 'Please complete Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection page as expected.' (Site from CRA).                                                                                                                                                                                                                                          | (b) (4), (b) (6)                   | 03 Dec 2020 00:33:22 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                   | 23 Nov 2020 22:08:25 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                     | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:41:40 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

Visit date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                  | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                              | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)        | 18 Dec 2020 08:08:21 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'Updated' (Site from DM). | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:37:57 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 20 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).             | (b) (4), (b) (6)                   | 10 Dec 2020 07:05:27 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                   | 23 Nov 2020 22:08:25 |
| User entered '20 Nov 2020'                                                                                                                                                                                                                                                                                                                                                                             | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:41:40 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.      | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:08:25 |
| User entered 'Clinic (Clinic)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:41:40 |



US3342046

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:23**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
| User entered 'SICKD1' | System           | 20 Nov 2020 19:41:40 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Time of assessment (00:00-23:59)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered '12:58'      | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
| User entered '20 Nov 2020 12:58' | System           | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Height \(xxx.x\)](#)

| Audit                                    | User                        | Time (GMT)           |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 01 May 2021 22:06:05 |
| User signature succeeded.                | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:09:07 |
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)     | 20 Nov 2020 19:42:19 |
| DataPoint set to visible.                | (b) (4)<br>System           | 20 Nov 2020 19:41:40 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Weight (xxx.x)

| Audit                                    | User                        | Time (GMT)           |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 01 May 2021 22:06:05 |
| User signature succeeded.                | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:09:07 |
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)     | 20 Nov 2020 19:42:19 |
| DataPoint set to visible.                | (b) (4)<br>System           | 20 Nov 2020 19:41:40 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered '99.4' F     | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |



US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered 'Oral (Oral)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered '86'         | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
| User entered 'bpm' | System           | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered '14'         | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
| User entered 'breaths/min' | System           | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User entered '144'        | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
| User entered 'mmHg' | System           | 20 Nov 2020 19:42:19 |



US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                    | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.                                                                                                                                                                            | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                  | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:09:07 |
| User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | (b) (4), (b) (6)                   | 23 Nov 2020 13:28:10 |
| Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:34 |
| User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).  |                                    | 20 Nov 2020 19:42:19 |
| User entered '102'                                                                                                                                                                                   | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
| User entered 'mmHg' | System           | 20 Nov 2020 19:42:19 |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
|                   |                  |                      |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:06:05 |
|                   |                  |                      |

US3342046

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

[Was the physical examination performed?](#)

| Audit                                                                                                                                                                        | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                            | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.                                                                                                                                                    | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                          | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 15:56:45 |
| User closed query 'Per ETRTR, Please complete Blood Sample Collection for Inmmunologic Assessment of SARS-CoV-2 Infection. Page is blank atm.' (Site from CRA).              | (b) (4), (b) (6)                   | 07 Jan 2021 15:56:42 |
| Query 'Per ETRTR, Please complete Blood Sample Collection for Inmmunologic Assessment of SARS-CoV-2 Infection. Page is blank atm.' answered with 'Updated.' (Site from CRA). | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:38:52 |
| User opened query 'Per ETRTR, Please complete Blood Sample Collection for Inmmunologic Assessment of SARS-CoV-2 Infection. Page is blank atm.' (Site from CRA).              | (b) (4), (b) (6)                   | 09 Dec 2020 22:10:02 |
| User entered 'Yes (Y)'                                                                                                                                                       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:43:10 |

US3342046

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:23**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 15:56:45 |
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 19:43:10 |

US3342046

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 11 Aug 2021 22:22:23**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 15:58:09 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:37:15 |

US3342046

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 11 Aug 2021 22:22:23**

[Date of Collection](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 22:06:05 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 15:58:09 |
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 21:37:15 |



US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

[Was this visit performed?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 16:01:13 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:42:47 |

US3342046

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 16:01:13 |
| User entered '17 Dec 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:42:47 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:22:23

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

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.      | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)        | 07 Jan 2021 16:01:13 |
| User entered 'Clinic (Clinic)' | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:42:47 |

US3342046

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:22:23**

[Folder OID](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Data hard locked.      | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
| User entered 'SICKD28' | System           | 17 Dec 2020 20:42:47 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Were vital signs assessed?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:23**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered '17 Dec 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:23**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered '13:55'      | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:23**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
| User entered '17 Dec 2020 13:55' | System           | 17 Dec 2020 20:44:38 |



US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Height (xxx.x)

| Audit                                    | User                        | Time (GMT)           |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 01 May 2021 20:25:08 |
| User signature succeeded.                | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 21:08:08 |
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)     | 17 Dec 2020 20:44:38 |
| DataPoint set to visible.                | (b) (4)<br>System           | 17 Dec 2020 20:42:47 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Weight (xxx.x)

| Audit                                    | User                        | Time (GMT)           |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 01 May 2021 20:25:08 |
| User signature succeeded.                | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 21:08:08 |
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)     | 17 Dec 2020 20:44:38 |
| DataPoint set to visible.                | (b) (4)<br>System           | 17 Dec 2020 20:42:47 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Temperature (xxx.x)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered '98.2' F     | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Route of measurement](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered 'Oral (Oral)' | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[If Other, specify](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse \(xxx\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered '71'         | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
| User entered 'bpm' | System           | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered '12'         | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |



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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
| User entered 'breaths/min' | System           | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Systolic Blood Pressure (xxx)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User entered '160'        | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

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**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:22:23**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
| User entered 'mmHg' | System           | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Diastolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                | User                               | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                    | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.                                                                                                                                                                            | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                  | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:08:08 |
| User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | (b) (4), (b) (6)                   | 18 Dec 2020 13:17:09 |
| Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:57 |
| User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).  |                                    | 17 Dec 2020 20:44:38 |
| User entered '103'                                                                                                                                                                                   | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
| User entered 'mmHg' | System           | 17 Dec 2020 20:44:38 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:25:08 |
|                   |                  |                      |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:22:23

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:25:08 |

US3342046

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:22:23

[Was the physical examination performed?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:09:18 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:45:06 |



US3342046

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:22:23**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 21:09:18 |
| User entered '17 Dec 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:45:06 |

US3342046

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:22:23

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                                                                                                                           | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                               | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.                                                                                                       | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| User closed query 'Source is empty. Please review and update as necessary ' (Site from CRA).                                    | (b) (4)<br>(b) (4), (b) (6)        | 18 Mar 2021 18:52:01 |
| DataPoint Verified.                                                                                                             | (b) (4), (b) (6)                   | 18 Mar 2021 18:37:07 |
| Query 'Source is empty. Please review and update as necessary ' answered with 'Source updated to reflect EDC.' (Site from CRA). | Ethan Shotton (b) (4)<br>(b) (4)   | 15 Mar 2021 17:46:40 |
| User opened query 'Source is empty. Please review and update as necessary ' (Site from CRA).                                    | (b) (4), (b) (6)                   | 04 Mar 2021 21:11:31 |
| User entered 'Yes (Y)'                                                                                                          | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:45:30 |

US3342046

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:22:23

[Date of Collection](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | User                               | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                   | 01 May 2021 20:25:08 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Paul Pickrell (b) (4)              | 22 Mar 2021 13:27:06 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | (b) (4)<br>(b) (4), (b) (6)        | 18 Mar 2021 18:37:07 |
| User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 17 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum 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 the tracking details in the response. Thank you.' (Site from DM).                                           | (b) (4), (b) (6)                   | 18 Jan 2021 11:51:52 |
| Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 17 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum 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 the tracking details in the response. Thank you.' answered with 'this has been reconciled in Preclarus' (Site from DM). | Eileen Euperio (b) (4)<br>(b) (4)  | 14 Jan 2021 16:36:16 |
| User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 17 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum 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 the tracking details in the response. Thank you.' (Site from DM).                                           | (b) (4), (b) (6)                   | 22 Dec 2020 10:18:43 |
| User entered '17 Dec 2020'                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Darrell O'Brien (b) (4)<br>(b) (4) | 17 Dec 2020 20:45:30 |

US3342046

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:22:23

[Did the participant experience any adverse events?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Joint aches in several joints, Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.<br>' (Site from DM).              | (b) (4), (b) (6)                   | 20 Apr 2021 12:33:25 |
| Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Joint aches in several joints, Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.<br>' answered with 'Updated.' (Site from DM). | Ethan Shotton (b) (4)<br>(b) (4)   | 19 Apr 2021 15:45:18 |
| User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Joint aches in several joints, Muscle aches all over, lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.<br>' (Site from DM).              | (b) (4), (b) (6)                   | 17 Apr 2021 08:55:27 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Paul Pickrell (b) (4)<br>(b) (4)   | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                   | 23 Nov 2020 19:50:05 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:29:18 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[AEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                             | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 21:29:09 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 01 Dec 2020 17:51:56 |
| User entered<br>'USA-US203-2020-mRNA-1273-P301000008' | System                      | 01 Dec 2020 17:51:33 |
| User entered 'New'                                    | (b) (4), (b) (6)            | 01 Dec 2020 17:51:33 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Adverse event](#)

| Audit                                                                                                                                                                                                                                    | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                        | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| 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)    | 23 Nov 2020 20:04:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                              | Coder Import (b) (4)    | 23 Nov 2020 20:04:09 |
| DataPoint Verified.                                                                                                                                                                                                                      | (b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| Data point term sent to Coder                                                                                                                                                                                                            | System                  | 23 Nov 2020 18:28:44 |
| Coding entries removed.                                                                                                                                                                                                                  | Stefanie Mott (b) (4)   | 23 Nov 2020 18:28:28 |
| User entered 'symptomatic covid-19 infection' reason for change: Data Entry Error                                                                                                                                                        | Stefanie Mott (b) (4)   | 23 Nov 2020 18:28:28 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\23.0. | Coder Import (b) (4)    | 20 Nov 2020 20:35:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                              | Coder Import (b) (4)    | 20 Nov 2020 20:35:02 |
| Data point term sent to Coder                                                                                                                                                                                                            | System                  | 20 Nov 2020 20:33:55 |
| User entered 'Viral URI'                                                                                                                                                                                                                 | Darrell O'Brien (b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Was this a medically-attended AE?](#)

| Audit                                                      | User                               | Time (GMT)           |
|------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                          | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 22:48:41 |
| User entered 'No (N)'                                      | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |



US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                                                      | User                               | Time (GMT)           |
|------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                          | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Stefanie Mott (b) (4)              | 23 Nov 2020 18:31:49 |
| User entered 'No (N)'                                      | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                    | User                               | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| User closed query 'Narrative below state onset of symptoms as 19Nov2020. Include the symptoms that started on 17Nov2020 in the narrative as well. AE date and onset of symptoms should be the same date. Please clarify or update as needed' (Site from CRA).                                                            | (b) (4)<br>(b) (4), (b) (6)        | 24 Nov 2020 21:48:02 |
| Query 'Narrative below state onset of symptoms as 19Nov2020. Include the symptoms that started on 17Nov2020 in the narrative as well. AE date and onset of symptoms should be the same date. Please clarify or update as needed' answered with 'UPDATED NARRATIVE TO ICLUDE SYMPTOMS STARTING ON 17NOV' (Site from CRA). | Eileen Euperio (b) (4)<br>(b) (4)  | 24 Nov 2020 20:00:36 |
| User opened query 'Narrative below state onset of symptoms as 19Nov2020. Include the symptoms that started on 17Nov2020 in the narrative as well. AE date and onset of symptoms should be the same date. Please clarify or update as needed' (Site from CRA).                                                            | (b) (4), (b) (6)                   | 23 Nov 2020 22:44:22 |
| Query 'Narrative below state onset of symptoms as 19Nov2020. AE date and onset of symptoms should be the same date. Please clarify or update as needed.' canceled (Site from CRA).                                                                                                                                       | (b) (4), (b) (6)                   | 23 Nov 2020 22:42:02 |
| User opened query 'Narrative below state onset of symptoms as 19Nov2020. AE date and onset of symptoms should be the same date. Please clarify or update as needed.' (Site from CRA).                                                                                                                                    | (b) (4), (b) (6)                   | 23 Nov 2020 20:14:23 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)                   | 23 Nov 2020 19:51:42 |
| User closed query 'Future date has been entered. Please correct.' (Site from System).                                                                                                                                                                                                                                    | System                             | 20 Nov 2020 20:38:29 |
| User entered '17 Nov 2020' reason for change: Data Entry Error                                                                                                                                                                                                                                                           | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:38:29 |
| User opened query 'Future date has been entered. Please correct.' (Site from System).                                                                                                                                                                                                                                    | System                             | 20 Nov 2020 20:32:57 |
| User entered '17 Nov 2302'                                                                                                                                                                                                                                                                                               | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

Start time (00:00-23:59)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Ongoing?](#)

| Audit                                                                                                                | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                    | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User closed query 'Source states yes. Please review and update as necessary' (Site from CRA).                        | (b) (4), (b) (6)        | 18 Mar 2021 16:21:40 |
| DataPoint Verified.                                                                                                  | (b) (4), (b) (6)        | 18 Mar 2021 16:21:32 |
| User signature succeeded.                                                                                            | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| Query 'Source states yes. Please review and update as necessary' answered with 'AE source updated.' (Site from CRA). | (b) (4)                 | 11 Mar 2021 16:13:59 |
| User opened query 'Source states yes. Please review and update as necessary' (Site from CRA).                        | (b) (4), (b) (6)        | 04 Mar 2021 21:47:36 |
| DataPoint Un-verified.                                                                                               | Eileen Euperio (b) (4)  | 14 Jan 2021 16:08:12 |
| User entered 'No (N)' reason for change: Data Entry Error                                                            | (b) (4)                 | 14 Jan 2021 16:08:12 |
| DataPoint Verified.                                                                                                  | (b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Yes (Y)'                                                                                               | Darrell O'Brien (b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                    | (b) (4), (b) (6)                  | 18 Mar 2021 16:21:49 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                              | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User closed query 'PV Query: Please clarify additional information received, from 28COV, as symptoms never entirely resolved, please advise if event is ongoing rather than resolved on 26 Dec. If so, please update outcome, end date and symptom logs accordingly. ? ' (Site from Safety).                                                                           | (b) (4)<br>(b) (4), (b) (6)       | 09 Feb 2021 22:27:13 |
| Query 'PV Query: Please clarify additional information received, from 28COV, as symptoms never entirely resolved, please advise if event is ongoing rather than resolved on 26 Dec. If so, please update outcome, end date and symptom logs accordingly. ? ' answered with 'D28 RESULTS NEGATIVE, SYMPTOMS WERE RESOLVED 26DEC PER SUBJECT REPORT' (Site from Safety). | Eileen Euperio (b) (4)<br>(b) (4) | 01 Feb 2021 21:03:02 |
| User opened query 'PV Query: Please clarify additional information received, from 28COV, as symptoms never entirely resolved, please advise if event is ongoing rather than resolved on 26 Dec. If so, please update outcome, end date and symptom logs accordingly. ? ' (Site from Safety).                                                                           | (b) (4), (b) (6)                  | 26 Jan 2021 16:28:22 |
| Query 'PV Query: Please clarify additional information received, from 28COV, as symptoms never entirely resolved, please advise if event is ongoing rather than resolved on 26 Dec. If so, please update outcome, end date and symptom logs accordingly.' canceled (Site from Safety).                                                                                 | (b) (4), (b) (6)                  | 26 Jan 2021 16:28:06 |
| User opened query 'PV Query: Please clarify additional information received, from 28COV, as symptoms never entirely resolved, please advise if event is ongoing rather than resolved on 26 Dec. If so, please update outcome, end date and symptom logs accordingly.' (Site from Safety).                                                                              | (b) (4), (b) (6)                  | 26 Jan 2021 16:26:39 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).                                                                                                                                                            | (b) (4), (b) (6)                  | 15 Jan 2021 17:39:47 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

If not Ongoing, end date (dd MMM yyyy)

| 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.' answered with 'updated with end date' (Site from Safety).<br>DataPoint Un-verified. | Eileen Euperio (b) (4)<br>(b) (4)    | 14 Jan 2021 16:20:37 |
|                                                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4)    | 14 Jan 2021 16:08:12 |
| User entered '26 Dec 2020' reason for change: Data Entry Error                                                                                                                                                                                                  | Eileen Euperio (b) (4)<br>(b) (4)    | 14 Jan 2021 16:08:12 |
| 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).<br>DataPoint Verified.                              | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 08 Dec 2020 19:13:27 |
|                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)<br>(b) (4)          | 23 Nov 2020 19:51:42 |
| User entered empty.                                                                                                                                                                                                                                             | Darrell O'Brien (b) (4)<br>(b) (4)   | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

End time (00:00-23:59)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |



US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Severity](#)

| Audit                                              | User                               | Time (GMT)           |
|----------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                          | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Is the adverse event serious?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Death](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |



US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Admitted to ICU?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Number of Days in ICU](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Relationship to investigational product](#)

| Audit                                    | User                               | Time (GMT)           |
|------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Not Related (NOT RELATED)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Relationship to Study Procedure](#)

| Audit                                    | User                               | Time (GMT)           |
|------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Not Related (NOT RELATED)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

Action taken with investigational product

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                           | User                    | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                               | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User closed query 'Source states none. Please review and reconcile. ' (Site from CRA).                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)        | 18 Mar 2021 16:22:13 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)        | 18 Mar 2021 16:22:07 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                                                       | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| Query 'Source states none. Please review and reconcile. ' answered with 'Source updated.' (Site from CRA).                                                                                                                                                                                                                                                                                                                      | Ethan Shotton (b) (4)   | 11 Mar 2021 15:49:39 |
| User opened query 'Source states none. Please review and reconcile. ' (Site from CRA).                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)        | 04 Mar 2021 21:40:07 |
| User closed query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).                                                                                                                                                                       | (b) (4), (b) (6)        | 01 Dec 2020 14:26:15 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                                                                                          | Morgan Schulle (b) (4)  | 30 Nov 2020 18:53:19 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                              | Morgan Schulle (b) (4)  | 30 Nov 2020 18:53:19 |
| Query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'This clinical event occurred after the first dose of investigational product. The first dose was administered on 13 AUG 2020. This event occurred on 17 NOV 2020.' (Site from DM). | Morgan Schulle (b) (4)  | 30 Nov 2020 15:29:52 |
| User opened query 'Per CDM: Per CCGs p. 33, Relationship to investigational product is expected to be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).                                                                                                                                                                       | (b) (4), (b) (6)        | 26 Nov 2020 06:21:00 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'None (NONE)'                                                                                                                                                                                                                                                                                                                                                                                                      | Darrell O'Brien (b) (4) | 20 Nov 2020 20:32:57 |



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

None

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Medication](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '1'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

US3342046

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Procedure](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Outcome](#)

| Audit                                                                                                                                                                                                                                    | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                        | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User closed query 'Source states recovering/resolving. Please review and update as necessary.' (Site from CRA).<br>DataPoint Verified.                                                                                                   | (b) (4), (b) (6)        | 18 Mar 2021 16:22:22 |
| User signature succeeded.                                                                                                                                                                                                                | (b) (4), (b) (6)        | 18 Mar 2021 16:22:20 |
| Query 'Source states recovering/resolving. Please review and update as necessary.' answered with 'Source updated.' (Site from CRA).                                                                                                      | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User opened query 'Source states recovering/resolving. Please review and update as necessary.' (Site from CRA).                                                                                                                          | (b) (4)                 | (b) (4)              |
| 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). | Ethan Shotton (b) (4)   | 11 Mar 2021 15:49:52 |
| User opened query 'Source states recovering/resolving. Please review and update as necessary.' (Site from CRA).                                                                                                                          | (b) (4)                 | (b) (4)              |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6)        | 04 Mar 2021 21:40:46 |
| 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)        | 15 Jan 2021 17:39:51 |
| DataPoint Un-verified.                                                                                                                                                                                                                   | Eileen Euperio (b) (4)  | 14 Jan 2021 16:20:45 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error                                                                                                                                               | (b) (4)                 | (b) (4)              |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | Eileen Euperio (b) (4)  | 14 Jan 2021 16:08:12 |
| DataPoint Verified.                                                                                                                                                                                                                      | Eileen Euperio (b) (4)  | 14 Jan 2021 16:08:12 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'                                                                                                                                                                               | (b) (4), (b) (6)        | 08 Dec 2020 19:13:16 |
|                                                                                                                                                                                                                                          | (b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
|                                                                                                                                                                                                                                          | Darrell O'Brien (b) (4) | 20 Nov 2020 20:32:57 |
|                                                                                                                                                                                                                                          | (b) (4)                 |                      |

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User                  | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User closed query 'Please provide narrative documentation for review' (Site from CRA).                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)      | 18 Mar 2021 17:25:36 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)      | 18 Mar 2021 17:24:59 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| Query 'Please provide narrative documentation for review' answered with 'Narrative updated to reflect source.' (Site from CRA).                                                                                                                                                                                                                                                                                                                                                                                                                              | Ethan Shotton (b) (4) | 11 Mar 2021 16:13:40 |
| User entered 'PT REPORTS SX OF COUGH, FATIGUE, & SNEEZING ONSET 17NOV2020 & SX OF HA, BODY ACHES, CHILLS, & FV (100.5 F & 101 F) ONSET 19NOV2020. ALL SX ONGOING AT ILLNESS VISIT (20NOV2020 @1300). PT REPORTS HAVING TAKEN ACETAMINOPHEN 975MG PO PRN FOR BODY ACHES ON 19NOV2020, CURRENTLY ONGOING MEDICATION AS PT PLANS TO TAKE ADDITIONAL DOSES THROUGHOUT ILLNESS. (PT INSTRUCTED TO COME IN FOR ILLNESS VISIT. ILLNESS VISIT COMPLETED.) DAO 20NOV2020                                                                                              | Ethan Shotton (b) (4) | 11 Mar 2021 16:13:07 |
| UPDATE: PT CAME IN FOR DAY 28CONV F/U APPT. PT ONLY SX @ VISIT MILD FATIGUE & MUSCLE ACHES. (SUBJECT HAD PREVIOUSLY REPORTAD @ MULTIPLE DAILY TELE-HEALTH VISITS AS HAVING NO SYMPTOMS (PER AE SOURCE). PT HAD ELEVATED BP@ DAY 28 CONVALESCENT VISIT F/U (160/103). HR 71 BPM. PT HAS NO DIAGNOSIS OF HTN AND NO RX. PT IS F/U W/ PCP TO MONITOR ELEVATED BP DUE TO POSITIVE COVID RESULT (PER ELEVATED BP AE SOURCE) SUBJECT ALSO REPORTS KNOWN EXPOSURE TO SOMEONE W/ COVID-19 ON 24NOV2020 (PER COVID-19 AE SOURCE).' reason for change: New Information | (b) (4), (b) (6)      | 04 Mar 2021 21:51:34 |
| User opened query 'Please provide narrative documentation for review' (Site from CRA).                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)      |                      |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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[Narrative](#)

| Audit                                                                                                                                                                                       | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'PV Query: Please clarify why an additional mRNA-1273 dosage was reported on 28 Dec 2020, after subject had already received both scheduled doses? ?' (Site from Safety). | (b) (4), (b) (6)       | 09 Feb 2021 22:28:00 |
| Query 'PV Query: Please clarify why an additional mRNA-1273 dosage was reported on 28 Dec 2020, after subject had already received both scheduled doses? ?'                                 | Eileen Euperio (b) (4) | 01 Feb 2021 21:03:37 |
| ' answered with 'SUBJECT RECEIVED VACCINE OUTSIDE OF STUDY AGAINST SITE'S ADVICE TO WAIT FOR UNBLINDING.' (Site from Safety).                                                               |                        |                      |
| User opened query 'PV Query: Please clarify why an additional mRNA-1273 dosage was reported on 28 Dec 2020, after subject had already received both scheduled doses? ?'                     | (b) (4), (b) (6)       | 26 Jan 2021 16:28:51 |
| ' (Site from Safety).                                                                                                                                                                       |                        |                      |
| Query 'PV Query: Please clarify why an additional mRNA-1273 dosage was reported on 28 Dec 2020, after subject had already received both scheduled doses?' canceled (Site from Safety).      | (b) (4), (b) (6)       | 26 Jan 2021 16:28:35 |
| User opened query 'PV Query: Please clarify why an additional mRNA-1273 dosage was reported on 28 Dec 2020, after subject had already received both scheduled doses?' (Site from Safety).   | (b) (4), (b) (6)       | 26 Jan 2021 16:26:09 |
| User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. If unknown please state so.' (Site from Safety).                                             | (b) (4), (b) (6)       | 15 Jan 2021 17:39:53 |

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[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User                    | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. If unknown please state so.' answered with 'UPDATED INFO' (Site from Safety).                                                                                                                                                                                                                                                                                                                             | Eileen Euperio (b) (4)  | 14 Jan 2021 16:25:05 |
| User entered 'PATIENT REPORTS SYMPTOMS OF COUGH, FATIGUE, AND SNEEZING ONSET 17NOV2020. PATIENT REPORTS SX OF HA, BODY ACHES, CHILLS, AND FV (100.5 AND 101 DEGREES F) ONSET OF 19NOV2020, ALL SX ONGOING AT ILLNESS VISIT (20NOV2020 @1300). PT REPORTS HAVING TAKEN ACETAMINOPHEN 975MG PO PRN FOR BODY ACHES ON 19NOV2020, ONGOING MEDICATION AS PT PLANS TO TAKE ADDITIONAL DOSES THROUGHOUT ILLNESS. PT INSTRUCTED TO COME IN FOR ILLNESS VISIT. ILLNESS VISIT COMPLETED. DAO 20NOV2020 | Eileen Euperio (b) (4)  | 14 Jan 2021 16:24:17 |
| UPDATE: PT CAME IN FOR DAY 28CONV F/U APPT WITH C/O MILD FATIGUE AND MILD MYALGIA. PT PREVIOUSLY REPORTED NO SX, BUT PROVIDED DIFFERENT INFORMATION AT IN-CLINIC VISIT, STATING THAT SX NEVER ENTIRELY RESOLVED. PT HYPERTENSIVE AT VISIT AND STATES THAT HE IS BEING FOLLOWED BY PHYSICIAN TO MONITOR AS COMPLICATION TO COVID INFECTION. SUBJECT REPORTED TO SITE KNOWN EXPOSURE TO A PERSON WITH COVID-19 ON 24NOV2020' reason for change: New Information<br>DataPoint Un-verified.      | Darrell O'Brien (b) (4) | 17 Dec 2020 20:51:40 |



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[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | User                    | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| User entered 'PATIENT REPORTS SYMPTOMS OF COUGH, FATIGUE, AND SNEEZING ONSET 17NOV2020. PATIENT REPORTS SX OF HA, BODY ACHES, CHILLS, AND FV (100.5 AND 101 DEGREES F) ONSET OF 19NOV2020, ALL SX ONGOING AT ILLNESS VISIT (20NOV2020 @1300). PT REPORTS HAVING TAKEN ACETAMINOPHEN 975MG PO PRN FOR BODY ACHES ON 19NOV2020, ONGOING MEDICATION AS PT PLANS TO TAKE ADDITIONAL DOSES THROUGHOUT ILLNESS. PT INSTRUCTED TO COME IN FOR ILLNESS VISIT. ILLNESS VISIT COMPLETED. DAO 20NOV2020' Update: Pt came in for Day 28Conv F/U appt with c/o mild fatigue and mild myalgia. Pt previously reported no Sx, but provided different information at in-clinic visit, stating that Sx never entirely resolved. Pt hypertensive at visit and states that he is being followed by physician to monitor as complication to covid infection. DAO 17DEC2020' reason for change: New Information | Darrell O'Brien (b) (4) | 17 Dec 2020 20:51:40 |
| User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. If unknown please state so.' (Site from Safety). DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)        | 08 Dec 2020 19:13:41 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)        | 24 Nov 2020 21:48:07 |
| User entered 'PATIENT REPORTS SYMPTOMS OF COUGH, FATIGUE, AND SNEEZING ONSET 17NOV2020. PATIENT REPORTS SX OF HA, BODY ACHES, CHILLS, AND FV (100.5 AND 101 DEGREES F) ONSET OF 19NOV2020, ALL SX ONGOING AT ILLNESS VISIT (20NOV2020 @1300). PT REPORTS HAVING TAKEN ACETAMINOPHEN 975MG PO PRN FOR BODY ACHES ON 19NOV2020, ONGOING MEDICATION AS PT PLANS TO TAKE ADDITIONAL DOSES THROUGHOUT ILLNESS. PT INSTRUCTED TO COME IN FOR ILLNESS VISIT. ILLNESS VISIT COMPLETED. DAO 20NOV2020' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                          | Eileen Euperio (b) (4)  | 24 Nov 2020 20:00:21 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | (b) (4)                 | 24 Nov 2020 20:00:21 |

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[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)        | 23 Nov 2020 19:51:42 |
| User entered 'Patient reports sx of cough, fatigue, and sneezing (onset 19Nov2020) and sx of ha, body aches, chills, and fv (100.5 and 101 degrees F) onset of 19nov2020, all sx ongoing at illness visit (20nov2020 @1300). Pt reports having taken acetaminophen 975mg po prn for body aches on 19nov2020, ongoing medication as pt plans to take additional doses throughout illness. Pt instructed to come in for illness visit. Illness visit completed. DAO 20NOV2020' | Darrell O'Brien (b) (4) | 20 Nov 2020 20:32:57 |

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '0'  | System           | 20 Nov 2020 20:32:57 |

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**Form:** Adverse Events (1)

**Generated On:** 11 Aug 2021 22:22:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 20 Nov 2020 22:48:41 |
| User entered '0'  | System           | 20 Nov 2020 20:32:57 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:22:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Adverse event](#)

| Audit                                                                                                                                                                                                                                          | User                    | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                              | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                      | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0. | Coder Import (b) (4)    | 18 Dec 2020 00:13:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                   | Coder Import (b) (4)    | 18 Dec 2020 00:13:52 |
| Data point term sent to Coder                                                                                                                                                                                                                  | System                  | 18 Dec 2020 00:13:10 |
| User entered 'Elevated Blood Pressure'                                                                                                                                                                                                         | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Was this a medically-attended AE?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |



US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                    | Time (GMT)           |
|----------------------------|-------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '17 Dec 2020' | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

Start time (00:00-23:59)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| User entered empty.       | (b) (4)<br>Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Ongoing?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'Yes (Y)'    | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

If not Ongoing, end date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

End time (00:00-23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |



US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Severity](#)

| Audit                                          | User                    | Time (GMT)           |
|------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.                      | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Is the adverse event serious?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Death](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |



US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Admitted to ICU?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Number of Days in ICU](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Relationship to investigational product](#)

| Audit                                    | User                    | Time (GMT)           |
|------------------------------------------|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.                | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'Not Related (NOT RELATED)' | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Relationship to Study Procedure](#)

| Audit                                    | User                    | Time (GMT)           |
|------------------------------------------|-------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.                | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'Not Related (NOT RELATED)' | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Action taken with investigational product](#)

| Audit                                          | User                               | Time (GMT)           |
|------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                      | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |



US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[None](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '1'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Medication](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Procedure](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered '0'          | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Outcome](#)

| Audit                                                                  | User                    | Time (GMT)           |
|------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| User entered empty.       | Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Narrative](#)

| Audit                                                                                                                                                                                                         | User                               | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                             | (b) (4), (b) (6)                   | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                     | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| User entered 'Pt had elevated blood pressure @ Day 28 Convalescent Visit F/UI (160/103). HR 71 bpm. Pt no Hx of HTN or Rx. Pt is f/u with PCP to monitor elevated BP due to + COVID 19 result. DAO 17DEC2020' | (b) (4)<br>Darrell O'Brien (b) (4) | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '0'  | System           | 18 Dec 2020 00:12:15 |

US3342046

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:22:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 18 Dec 2020 00:12:15 |



US3342046

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 11 Aug 2021 22:22:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:35 |
|                   |                  |                      |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Adverse event](#)

| Audit                                                                                                                                                                       | User                  | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                           | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.                                                                                                                                                   | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0. | Coder Import (b) (4)  | 19 Apr 2021 15:43:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                | Coder Import (b) (4)  | 19 Apr 2021 15:43:38 |
| Data point term sent to Coder                                                                                                                                               | System                | 19 Apr 2021 15:42:40 |
| User entered 'Myalgia'                                                                                                                                                      | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Was this a medically-attended AE?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '19 Sep 2020' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

Start time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 12:49:35 |
| User entered empty. | System           | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '24 Sep 2020' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

End time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 12:49:35 |
| User entered empty. | System           | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Severity](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Is the adverse event serious?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |



US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Admitted to ICU?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Number of Days in ICU](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |



US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Relationship to investigational product](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.        | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Related (RELATED)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Relationship to Study Procedure](#)

| Audit                                    | User                  | Time (GMT)           |
|------------------------------------------|-----------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.                | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Not Related (NOT RELATED)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.                      | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[None](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '1'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Medication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Procedure](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Outcome](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded.                              | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:22:23

[Narrative](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:35 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:42:09 |

US3342046

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 11 Aug 2021 22:22:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:35 |
| User entered '0'  | System           | 19 Apr 2021 15:42:09 |

US3342046

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 11 Aug 2021 22:22:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:35 |
| User entered '0'  | System           | 19 Apr 2021 15:42:09 |

US3342046

**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 11 Aug 2021 22:22:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:35 |
|                   |                  |                      |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:41 |
|                   |                  |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Adverse event](#)

| Audit                                                                                                                                                                                                    | User                  | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                        | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.                                                                                                                                                                                | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Polyarthralgia - version MedDRA\\23.0. | Coder Import (b) (4)  | 19 Apr 2021 15:45:32 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                             | Coder Import (b) (4)  | 19 Apr 2021 15:45:32 |
| Data point term sent to Coder                                                                                                                                                                            | System                | 19 Apr 2021 15:44:42 |
| User entered 'Polyarthralgia'                                                                                                                                                                            | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Was this a medically-attended AE?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '19 Sep 2020' | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

Start time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 12:49:41 |
| User entered empty. | System           | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                  | User                  | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                      | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.                                                                                                                                              | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | (b) (4)               | 19 Apr 2021 15:45:08 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System                | 19 Apr 2021 15:45:08 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).                                                                        | System                | 19 Apr 2021 15:45:08 |
| User entered '24 Sep 2020' reason for change: Data Entry Error                                                                                                         | Ethan Shotton (b) (4) | 19 Apr 2021 15:45:08 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | (b) (4)               | 19 Apr 2021 15:44:20 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).                                                                        | System                | 19 Apr 2021 15:44:20 |
| User entered empty.                                                                                                                                                    | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |
|                                                                                                                                                                        | (b) (4)               |                      |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

End time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 12:49:41 |
| User entered empty. | System           | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Severity](#)

| Audit                                      | User                  | Time (GMT)           |
|--------------------------------------------|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.                  | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Is the adverse event serious?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'No (N)'     | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Admitted to ICU?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Number of Days in ICU](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Relationship to investigational product](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.        | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Related (RELATED)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Relationship to Study Procedure](#)

| Audit                                    | User                  | Time (GMT)           |
|------------------------------------------|-----------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.                | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Not Related (NOT RELATED)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Action taken with investigational product](#)

| Audit                                          | User                  | Time (GMT)           |
|------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.                      | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |



US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[None](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '1'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Medication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Concomitant Procedure](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered '0'          | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Outcome](#)

| Audit                                                  | User                  | Time (GMT)           |
|--------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded.                              | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Narrative](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 30 Apr 2021 12:49:41 |
| User signature succeeded. | Paul Pickrell (b) (4) | 28 Apr 2021 16:30:56 |
| User entered empty.       | Ethan Shotton (b) (4) | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:41 |
| User entered '0'  | System           | 19 Apr 2021 15:44:20 |

US3342046

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:22:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:41 |
| User entered '0'  | System           | 19 Apr 2021 15:44:20 |



US3342046

**Folder:** Adverse Events

**Form:** Adverse Events (4)

**Generated On:** 11 Aug 2021 22:22:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:49:41 |
|                   |                  |                      |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:22:23**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:42 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:07:01 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                             | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                         | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                               | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: RESPIRATORY<br>SYSTEM, ATC: ANTIHISTAMINES FOR<br>SYSTEMIC USE, ATC: ANTIHISTAMINES FOR<br>SYSTEMIC USE, ATC: OTHER<br>ANTIHISTAMINES FOR SYSTEMIC USE,<br>PRODUCT: LORATADINE,<br>PRODUCTSYNONYM: CLARITIN<br>[LORATADINE] - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 13 Aug 2020 15:10:28 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)   | 13 Aug 2020 15:10:28 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                     | System                            | 13 Aug 2020 15:08:48 |
| User entered 'claritin'                                                                                                                                                                                                                                                                           | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                             | User                              | Time (GMT)           |
|-----------------------------------|-----------------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.         | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.               | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'seasonal allergies' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '10'         | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'as needed (PRN)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:38:52 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:08:22 |
| User entered 'un UNK 2010'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 13 Aug 2020 15:08:22 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 13 Aug 2020 15:08:22 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                      | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                              | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                    | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>OTHER ANALGESICS AND ANTIPYRETICS,<br>PRODUCT: GABAPENTIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 00:34:15 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                             | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 00:34:15 |
| Data point term sent to Coder                                                                                                                                                                                          | System                            | 13 Aug 2020 15:09:53 |
| User entered 'gabapentin'                                                                                                                                                                                              | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                                   | User                              | Time (GMT)           |
|-----------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                       | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.               | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                     | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'cervical disk herniation' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '300'        | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'once daily (QD)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[If route of administration is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:38:59 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:09:02 |
| User entered 'un Feb 2020'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:09:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '804 (804)' | System           | 13 Aug 2020 15:09:02 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                              | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                  | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                          | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM - version<br>WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 07:00:14 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\202003.                                                                                                                                                          | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 07:00:14 |
| Data point term sent to Coder                                                                                                                                                                                                                                      | System                            | 13 Aug 2020 15:10:55 |
| User entered 'meloxicam'                                                                                                                                                                                                                                           | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                                   | User                              | Time (GMT)           |
|-----------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                       | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.               | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                     | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'cervical disk herniation' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '7.5'        | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'once daily (QD)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:39:06 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:10:00 |
| User entered 'un Feb 2020'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:10:00 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '804 (804)' | System           | 13 Aug 2020 15:10:00 |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                        | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                            | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                    | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                          | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>TIZANIDINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 18 Aug 2020 01:20:12 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)   | 18 Aug 2020 01:20:12 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                            | 17 Aug 2020 14:02:11 |
| Coding entries removed.                                                                                                                                                                                                                      | Tiffany Lemuz (b) (4)             | 17 Aug 2020 14:01:29 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>TIZANIDINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 03:53:15 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 03:53:15 |
| Data point term sent to Coder                                                                                                                                                                                                                | System                            | 13 Aug 2020 15:10:56 |
| User entered 'tizanadine'                                                                                                                                                                                                                    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:22:23

[Indication](#)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                    | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 17 Aug 2020 14:01:29 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 17 Aug 2020 14:01:29 |
| User entered 'Cervical disc herniation' reason for change: Data Entry Error            | Tiffany Lemuz (b) (4)             | 17 Aug 2020 14:01:29 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 13 Aug 2020 15:10:32 |
| User entered empty.                                                                    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '2'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'once daily (QD)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:39:15 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:10:32 |
| User entered 'un Feb 2020'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:10:32 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:10:32 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '804 (804)' | System           | 13 Aug 2020 15:10:32 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                            | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                                        | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                              | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS,<br>ATC: OPIOIDS IN COMBINATION WITH<br>NON-OPIOID ANALGESICS, PRODUCT:<br>OXYCODONE<br>HYDROCHLORIDE;PARACETAMOL,<br>PRODUCTSYNONYM: PERCOCET<br>[OXYCODONE<br>HYDROCHLORIDE;PARACETAMOL] - version<br>WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)   | 26 Aug 2020 13:21:42 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\202003.                                                                                                                                                                                                        | Coder Import (b) (4)<br>(b) (4)   | 26 Aug 2020 13:21:42 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                    | System                            | 26 Aug 2020 13:06:14 |
| Query 'CDM Coding: This medication can be<br>referred as multiple ingredients in the standard<br>coding dictionary. Please enter all the active<br>ingredient(s) with drug name in drug name field and<br>please make your changes to the reported term.<br>Thank you.' canceled (Site from System).             | Coder Import (b) (4)<br>(b) (4)   | 26 Aug 2020 13:05:39 |
| User opened query 'CDM Coding: This medication<br>can be referred as multiple ingredients in the standard<br>coding dictionary. Please enter all the active<br>ingredient(s) with drug name in drug name field and<br>please make your changes to the reported term.<br>Thank you.' (Site from System).          | Coder Import (b) (4)<br>(b) (4)   | 19 Aug 2020 11:28:14 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                    | System                            | 13 Aug 2020 15:11:56 |
| User entered 'percocet'                                                                                                                                                                                                                                                                                          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                                   | User                              | Time (GMT)           |
|-----------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                       | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.               | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                     | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'cervical disk herniation' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '325'        | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'as needed (PRN)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[If route of administration is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:39:22 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:11:02 |
| User entered 'un Feb 2020'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 13 Aug 2020 15:11:02 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered empty. | System           | 13 Aug 2020 15:11:02 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                       | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                           | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                   | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                         | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 13 Aug 2020 15:13:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                   | Coder Import (b) (4)<br>(b) (4)   | 13 Aug 2020 15:13:19 |
| Data point term sent to Coder                                                                                                                                                                                                               | System                            | 13 Aug 2020 15:11:58 |
| User entered 'multivitamin'                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'wellness'   | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '1'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'tablet (TABLET)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'once daily (QD)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:39:28 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:11:30 |
| User entered 'un UNK 2015'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:11:30 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '804 (804)' | System           | 13 Aug 2020 15:11:30 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                             | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                 | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                         | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                               | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 00:24:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.                                                                              | Coder Import (b) (4)<br>(b) (4)   | 14 Aug 2020 00:24:07 |
| Data point term sent to Coder                                                                                                                                                     | System                            | 13 Aug 2020 15:11:59 |
| User entered 'fish oil'                                                                                                                                                           | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'wellness'   | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '1000'       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'once daily (QD)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[If route of administration is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:22:23

Start date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                      | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                          | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)                  | 13 Aug 2020 21:39:34 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                            | 13 Aug 2020 15:11:56 |
| User entered 'un UNK 2015'                                                                                                                                                                                                                                 | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered '0'          | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered empty.       | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 13 Aug 2020 15:11:56 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '804 (804)' | System           | 13 Aug 2020 15:11:56 |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                  | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded.                                                                                                                                                                                                                                                              | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                                                                                    | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 09 Oct 2020 00:08:58 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.                                                                                                                                                                             | Coder Import (b) (4)<br>(b) (4)  | 09 Oct 2020 00:08:58 |
| Data point term sent to Coder                                                                                                                                                                                                                                                          | System                           | 08 Oct 2020 16:10:39 |
| User entered 'Ibuprofen'                                                                                                                                                                                                                                                               | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Indication](#)

| Audit                                               | User                             | Time (GMT)           |
|-----------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded.                           | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                 | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered 'Headache (solicited AR - vaccine #2)' | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered '200'        | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:22:23

[Dose unit](#)

| Audit                                                                                  | User                             | Time (GMT)           |
|----------------------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                                                      | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded.                                                              | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                    | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                           | 08 Oct 2020 16:10:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                           | 08 Oct 2020 16:10:33 |
| User entered 'mg (mg)' reason for change: Data Entry Error                             | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:33 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                           | 08 Oct 2020 16:10:28 |
| User entered empty.                                                                    | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered empty.       | Ethan Shotton (b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded.  | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered 'once (ONCE)' | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered empty.       | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded.  | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[If route of administration is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered empty.       | Ethan Shotton (b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded.  | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered '20 Sep 2020' | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered '0'          | Ethan Shotton (b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Ethan Shotton (b) (4)<br>(b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 01 May 2021 07:16:58 |
| User signature succeeded.  | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered '20 Sep 2020' | Ethan Shotton (b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 01 May 2021 07:16:58 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Ethan Shotton (b) (4) | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:16:58 |
| User entered empty. | System           | 08 Oct 2020 16:10:28 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:16:58 |
| User entered empty. | System           | 08 Oct 2020 16:10:28 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:16:58 |
| User entered empty. | System           | 08 Oct 2020 16:10:28 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                         | User                               | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                             | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded.                                                                                                                                                                                                     | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                                                                                                                                                                                           | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>ANILIDES, PRODUCT: PARACETAMOL,<br>PRODUCTSYNONYM: ACETAMINOPHEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 23 Nov 2020 20:06:02 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)<br>(b) (4)    | 23 Nov 2020 20:06:02 |
| Data point term sent to Coder                                                                                                                                                                                                 | System                             | 23 Nov 2020 18:30:47 |
| Coding entries removed.                                                                                                                                                                                                       | Stefanie Mott (b) (4)              | 23 Nov 2020 18:30:04 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>ANILIDES, PRODUCT: PARACETAMOL,<br>PRODUCTSYNONYM: ACETAMINOPHEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 20 Nov 2020 20:19:04 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.                                                                                                               | Coder Import (b) (4)<br>(b) (4)    | 20 Nov 2020 20:19:04 |
| Data point term sent to Coder                                                                                                                                                                                                 | System                             | 20 Nov 2020 20:18:29 |
| User entered 'Acetaminophen'                                                                                                                                                                                                  | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:22:23

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | User                    | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)        | 01 May 2021 07:17:16 |
| User signature succeeded.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Paul Pickrell (b) (4)   | 12 Mar 2021 23:15:11 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' canceled (Site from DM).    | (b) (4), (b) (6)        | 05 Jan 2021 13:48:51 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6)        | 05 Jan 2021 13:48:48 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | (b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered 'symptomatic covid-19 infection' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                                                                                                                       | Stefanie Mott (b) (4)   | 23 Nov 2020 18:30:04 |
| User entered 'Body Aches (Viral URI AE)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Darrell O'Brien (b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered '975'        | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded.      | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered 'as needed (PRN)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

If route of administration is Other, specify

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered empty.       | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded.  | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered '19 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded. | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)        | 23 Nov 2020 22:44:55 |
| User entered '0'          | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:22:23

[Ongoing?](#)

| Audit                                                     | User                        | Time (GMT)           |
|-----------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                         | (b) (4), (b) (6)            | 01 May 2021 07:17:16 |
| User signature succeeded.                                 | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 22:03:04 |
| DataPoint Un-verified.                                    | Stefanie Mott (b) (4)       | 30 Nov 2020 14:48:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Stefanie Mott (b) (4)       | 30 Nov 2020 14:48:27 |
| DataPoint Verified.                                       | (b) (4), (b) (6)            | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'                                    | Darrell O'Brien (b) (4)     | 20 Nov 2020 20:17:51 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:22:23

If not Ongoing, End date (dd MMM yyyy)

| Audit                                                          | User                               | Time (GMT)           |
|----------------------------------------------------------------|------------------------------------|----------------------|
| Data hard locked.                                              | (b) (4), (b) (6)                   | 01 May 2021 07:17:16 |
| User signature succeeded.                                      | Paul Pickrell (b) (4)              | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                            | (b) (4)<br>(b) (4), (b) (6)        | 04 Mar 2021 22:07:24 |
| DataPoint Un-verified.                                         | Stefanie Mott (b) (4)              | 30 Nov 2020 14:48:27 |
| User entered '26 Nov 2020' reason for change: Data Entry Error | Stefanie Mott (b) (4)              | 30 Nov 2020 14:48:27 |
| DataPoint Verified.                                            | (b) (4), (b) (6)                   | 23 Nov 2020 22:44:55 |
| User entered empty.                                            | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:17:51 |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:22:23

[Was this medication taken for solicited event?](#)

| Audit                                                     | User                        | Time (GMT)           |
|-----------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                         | (b) (4), (b) (6)            | 01 May 2021 07:17:16 |
| User signature succeeded.                                 | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 22:07:25 |
| DataPoint Un-verified.                                    | Stefanie Mott (b) (4)       | 30 Nov 2020 14:48:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Stefanie Mott (b) (4)       | 30 Nov 2020 14:48:27 |
| DataPoint Verified.                                       | (b) (4), (b) (6)            | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'                                    | Darrell O'Brien (b) (4)     | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:17:16 |
| User entered empty. | System           | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:17:16 |
| User entered empty. | System           | 20 Nov 2020 20:17:51 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:17:16 |
| User entered empty. | System           | 20 Nov 2020 20:17:51 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                       | User                  | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                           | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                   | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)  | 01 Dec 2020 00:15:00 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                                                                                                                    | Coder Import (b) (4)  | 01 Dec 2020 00:15:00 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System                | 01 Dec 2020 00:14:17 |
| Coding entries removed.                                                                                                                                                                                                                                                                     | Stefanie Mott (b) (4) | 01 Dec 2020 00:13:50 |
| DataPoint Verified.                                                                                                                                                                                                                                                                         | (b) (4), (b) (6)      | 23 Nov 2020 22:44:55 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)  | 23 Nov 2020 20:04:08 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                                                                                                                    | Coder Import (b) (4)  | 23 Nov 2020 20:04:08 |
| Data point term sent to Coder                                                                                                                                                                                                                                                               | System                | 23 Nov 2020 18:29:46 |
| User entered 'aspirin'                                                                                                                                                                                                                                                                      | Stefanie Mott (b) (4) | 23 Nov 2020 18:29:41 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                                                                                                                                                                                                                                                                                                      | User                                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                          | (b) (4), (b) (6)                     | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                                  | Paul Pickrell (b) (4)                | 12 Mar 2021 23:15:11 |
| User closed query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives/prophylactically indicated meds/hearth health indications and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' (Site from DM).                            | (b) (4)<br>(b) (4), (b) (6)          | 04 Dec 2020 14:02:36 |
| Query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives/prophylactically indicated meds/hearth health indications and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' answered with 'This has been updated.' (Site from DM). | Olivia Hapanowicz (b) (4)<br>(b) (4) | 03 Dec 2020 16:28:06 |
| DataPoint Un-verified.                                                                                                                                                                                                                                                                                     | Olivia Hapanowicz (b) (4)<br>(b) (4) | 03 Dec 2020 16:27:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                                                                                                                                                                 | Olivia Hapanowicz (b) (4)<br>(b) (4) | 03 Dec 2020 16:27:56 |
| User opened query 'Per CDM: Please review prophylaxis because supplements/vitamins/contraceptives/prophylactically indicated meds/hearth health indications and vaccines are considered as prophylaxis. Update as appropriate or clarify otherwise. Thank you!' (Site from DM).                            | (b) (4), (b) (6)                     | 03 Dec 2020 06:45:20 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                        | (b) (4), (b) (6)                     | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                                                                      | Stefanie Mott (b) (4)                | 23 Nov 2020 18:29:41 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:22:23

[Indication](#)

| Audit                                                                  | User                             | Time (GMT)           |
|------------------------------------------------------------------------|----------------------------------|----------------------|
| Data hard locked.                                                      | (b) (4), (b) (6)                 | 02 May 2021 14:05:09 |
| User signature succeeded.                                              | Paul Pickrell (b) (4)            | 12 Mar 2021 23:15:11 |
| DataPoint Un-verified.                                                 | (b) (4)<br>Stefanie Mott (b) (4) | 01 Dec 2020 00:13:50 |
| User entered 'cardiac prophylaxis' reason for change: Data Entry Error | Stefanie Mott (b) (4)            | 01 Dec 2020 00:13:50 |
| DataPoint Verified.                                                    | (b) (4), (b) (6)                 | 23 Nov 2020 22:44:55 |
| User entered 'symptomatic covid-19 infection'                          | Stefanie Mott (b) (4)            | 23 Nov 2020 18:29:41 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:22:23

[Dose per administration](#)

| Audit                                                                                                                                                                                                                                                                                               | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                                                   | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded.                                                                                                                                                                                                                                                                           | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                                                                        | (b) (4)<br>(b) (4), (b) (6)       | 15 Jan 2021 14:02:18 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'This is the dosage subject reported to site taking, he has since withdrawn consent' (Site from DM). | Eileen Euperio (b) (4)<br>(b) (4) | 14 Jan 2021 16:29:43 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).                                                                                        | (b) (4), (b) (6)                  | 05 Jan 2021 13:49:22 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                  | 23 Nov 2020 22:44:55 |
| User entered '243'                                                                                                                                                                                                                                                                                  | Stefanie Mott (b) (4)             | 23 Nov 2020 18:29:41 |



US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered 'mg (mg)'    | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:22:23

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.      | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered 'once daily (QD)' | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered 'Oral (ORAL)' | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.  | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered '21 Nov 2020' | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered '0'          | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:22:23

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered 'Yes (Y)'    | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered empty.       | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:44:55 |
| User entered 'No (N)'     | Stefanie Mott (b) (4)       | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '1'  | System           | 23 Nov 2020 18:29:41 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:29:41 |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                           | User                      | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                                                                                                                                               | (b) (4), (b) (6)          | 01 May 2021 07:17:10 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003. | Coder Import (b) (4)      | 22 Apr 2021 13:11:50 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                        | (b) (4)                   | 22 Apr 2021 13:11:50 |
| Data point term sent to Coder                                                                                                                                                                   | System                    | 22 Apr 2021 13:11:17 |
| Coding entries removed.                                                                                                                                                                         | Olivia Hapanowicz (b) (4) | 22 Apr 2021 13:10:22 |
| User signature succeeded.                                                                                                                                                                       | (b) (4)                   | 29 Mar 2021 15:02:48 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\202003. | Paul Pickrell (b) (4)     | 22 Mar 2021 15:26:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.                                                                                        | Coder Import (b) (4)      | 22 Mar 2021 15:26:47 |
| Data point term sent to Coder                                                                                                                                                                   | System                    | 22 Mar 2021 15:25:59 |
| Coding entries removed.                                                                                                                                                                         | Ethan Shotton (b) (4)     | 22 Mar 2021 15:25:07 |
| Coding entries removed.                                                                                                                                                                         | (b) (4)                   | 22 Mar 2021 15:25:07 |
| Signature has been broken.                                                                                                                                                                      | Ethan Shotton (b) (4)     | 22 Mar 2021 15:25:07 |
| User entered 'MRNA-1273 Vaccine' reason for change: Data Entry Error                                                                                                                            | (b) (4)                   | 22 Mar 2021 15:25:07 |
| User signature succeeded.                                                                                                                                                                       | Ethan Shotton (b) (4)     | 12 Mar 2021 23:15:11 |
| User closed query 'Per DM CLR: Please review if study medication should be removed from ConMed eCRF page. If so, update eCRF as appropriate or clarify.                                         | Paul Pickrell (b) (4)     | 03 Mar 2021 13:27:34 |
| ' (Site from DM).                                                                                                                                                                               | (b) (4)                   |                      |
|                                                                                                                                                                                                 | (b) (4), (b) (6)          |                      |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:22:23

[Name of Medication](#)

| Audit                                                                                                                                                                                                                      | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Query 'Per DM CLR: Please review if study medication should be removed from ConMed eCRF page. If so, update eCRF as appropriate or clarify.<br />' answered with 'done outside of study, will keep on CRF' (Site from DM). | Eileen Euperio (b) (4) | 02 Mar 2021 19:55:26 |
| User opened query 'Per DM CLR: Please review if study medication should be removed from ConMed eCRF page. If so, update eCRF as appropriate or clarify.                                                                    | (b) (4), (b) (6)       | 05 Feb 2021 09:32:09 |
| ' (Site from DM).                                                                                                                                                                                                          |                        |                      |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version                                                      | Coder Import (b) (4)   | 01 Feb 2021 18:29:29 |
| WHODrug-Global-B3\\202003.                                                                                                                                                                                                 |                        |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version                                                                                                                                                  | Coder Import (b) (4)   | 01 Feb 2021 18:29:29 |
| WHODrug-Global-B3\\202003.                                                                                                                                                                                                 |                        |                      |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, PRODUCT: VIRAL VACCINES - version                                                                                       | Coder Import (b) (4)   | 15 Jan 2021 15:10:52 |
| WHODrug-Global-B3\\202003.                                                                                                                                                                                                 |                        |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version                                                                                                                                                  | Coder Import (b) (4)   | 15 Jan 2021 15:10:52 |
| WHODrug-Global-B3\\202003.                                                                                                                                                                                                 |                        |                      |
| Data point term sent to Coder                                                                                                                                                                                              | System                 | 14 Jan 2021 16:28:40 |
| User entered 'MRNA-1273'                                                                                                                                                                                                   | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |
|                                                                                                                                                                                                                            | (b) (4)                |                      |



US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:22:23

[Prophylaxis](#)

| Audit                                                                                                                                                  | User                        | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                                                                      | (b) (4), (b) (6)            | 01 May 2021 07:17:10 |
| User signature succeeded.                                                                                                                              | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User closed query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medications used for prevention. Please reconcile, thank you. ' (Site from DM). | (b) (4)<br>(b) (4), (b) (6) | 20 Jan 2021 13:15:35 |
| Query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medications used for prevention. Please reconcile, thank you.                               | Olivia Hapanowicz (b) (4)   | 19 Jan 2021 22:17:05 |
| ' answered with 'Updated' (Site from DM).                                                                                                              | (b) (4)                     |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                             | Olivia Hapanowicz (b) (4)   | 19 Jan 2021 22:16:55 |
| User opened query 'Per CDM: Per CCGs pg 49, prophylaxis applies to any medications used for prevention. Please reconcile, thank you. ' (Site from DM). | (b) (4), (b) (6)            | 19 Jan 2021 19:03:32 |
| User entered 'No (N)'                                                                                                                                  | Eileen Euperio (b) (4)      | 14 Jan 2021 16:27:53 |
|                                                                                                                                                        | (b) (4)                     |                      |

US3342046

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:22:23

[Indication](#)

| Audit                                                                                                                                                        | User                        | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                                                                                                                            | (b) (4), (b) (6)            | 01 May 2021 07:17:10 |
| User signature succeeded.                                                                                                                                    | Paul Pickrell (b) (4)       | 28 Apr 2021 16:30:56 |
| User closed query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 17:33:40 |
| Query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' answered with 'updated' (Site from DM). | Olivia Hapanowicz (b) (4)   | 22 Apr 2021 13:10:46 |
| Signature has been broken.                                                                                                                                   | (b) (4)                     |                      |
| User entered 'COVID-19' reason for change: Data Entry Error                                                                                                  | Olivia Hapanowicz (b) (4)   | 22 Apr 2021 13:10:22 |
| User opened query 'Per CDM: The medication recorded is a COVID 19 vaccine. Please agree to update the indication to 'COVID 19'.' (Site from DM).             | (b) (4)                     |                      |
| User signature succeeded.                                                                                                                                    | (b) (4), (b) (6)            | 21 Apr 2021 18:00:40 |
| Signature has been broken.                                                                                                                                   | Paul Pickrell (b) (4)       | 29 Mar 2021 15:02:48 |
| User entered 'COVID-19 Prophylaxis' reason for change: Data Entry Error                                                                                      | (b) (4)                     |                      |
| User signature succeeded.                                                                                                                                    | Ethan Shotton (b) (4)       | 22 Mar 2021 15:25:07 |
| User entered 'WELLNESS'                                                                                                                                      | (b) (4)                     |                      |
|                                                                                                                                                              | Eileen Euperio (b) (4)      | 22 Mar 2021 15:25:07 |
|                                                                                                                                                              | (b) (4)                     |                      |
|                                                                                                                                                              | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
|                                                                                                                                                              | (b) (4)                     |                      |
|                                                                                                                                                              | Eileen Euperio (b) (4)      | 14 Jan 2021 16:27:53 |
|                                                                                                                                                              | (b) (4)                     |                      |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose per administration](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '100'        | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Dose unit](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'ug (ug)'    | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Frequency](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'once (ONCE)' | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[If frequency is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Route of administration](#)

| Audit                                        | User                   | Time (GMT)           |
|----------------------------------------------|------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded.                    | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[If route of administration is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '28 Dec 2020' | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '0'          | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

US3342046

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '28 Dec 2020' | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 07:17:10 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered 'No (N)'     | Eileen Euperio (b) (4) | 14 Jan 2021 16:27:53 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:17:10 |
| User entered empty. | System           | 14 Jan 2021 16:27:53 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:17:10 |
| User entered empty. | System           | 14 Jan 2021 16:27:53 |



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:22:23**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 07:17:10 |
| User entered empty. | System           | 14 Jan 2021 16:27:53 |

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:22:23**

[Were any concomitant procedures performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 04 Mar 2021 22:07:41 |
| User entered 'No (N)'     | Eileen Euperio (b) (4)<br>(b) (4) | 14 Jan 2021 16:36:41 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:22:23**

[Date of study discontinuation/completion \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 27 Apr 2021 12:33:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 31 Mar 2021 18:21:39 |
| User signature succeeded.  | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered '04 Jan 2021' | Eileen Euperio (b) (4) | 14 Jan 2021 16:26:21 |

US3342046

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:22:23

[Reason for discontinuation](#)

| Audit                                                                                                                                                                                                                                                                     | User                      | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|----------------------|
| Data hard locked.                                                                                                                                                                                                                                                         | (b) (4), (b) (6)          | 27 Apr 2021 12:33:53 |
| DataPoint Verified.                                                                                                                                                                                                                                                       | (b) (4), (b) (6)          | 31 Mar 2021 18:21:39 |
| User signature succeeded.                                                                                                                                                                                                                                                 | Paul Pickrell (b) (4)     | 29 Mar 2021 15:02:48 |
| User closed query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study prior to withdrawal of consent, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate. ' (Site from DM).               | (b) (4), (b) (6)          | 23 Mar 2021 13:10:08 |
| Query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study prior to withdrawal of consent, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate. ' answered with 'corrected' (Site from DM). | Olivia Hapanowicz (b) (4) | 22 Mar 2021 14:46:01 |
| Signature has been broken.                                                                                                                                                                                                                                                | Olivia Hapanowicz (b) (4) | 22 Mar 2021 14:45:45 |
| User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error                                                                                                                                                                      | Olivia Hapanowicz (b) (4) | 22 Mar 2021 14:45:45 |
| User opened query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study prior to withdrawal of consent, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate. ' (Site from DM).               | (b) (4), (b) (6)          | 22 Mar 2021 14:23:56 |
| User signature succeeded.                                                                                                                                                                                                                                                 | Paul Pickrell (b) (4)     | 12 Mar 2021 23:15:11 |
| User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'                                                                                                                                                                                     | Eileen Euperio (b) (4)    | 14 Jan 2021 16:26:21 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:22:23**

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

| Audit                                                                                                                               | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Data hard locked.                                                                                                                   | (b) (4), (b) (6)                  | 27 Apr 2021 12:33:53 |
| DataPoint Verified.                                                                                                                 | (b) (4), (b) (6)                  | 31 Mar 2021 18:21:39 |
| User signature succeeded.                                                                                                           | Paul Pickrell (b) (4)             | 12 Mar 2021 23:15:11 |
| User entered 'SUBJECT REPORTED GETTING MODERNA VACCINE ON 28DEC2020 AND EXPRESSED THAT HE NO LONGER WANTED TO PARTICIPATE IN STUDY' | (b) (4)<br>Eileen Euperio (b) (4) | 14 Jan 2021 16:26:21 |

US3342046

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:22:23**

[If reason for discontinuation is Death, main cause of death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:33:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 31 Mar 2021 18:21:39 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:26:21 |

US3342046

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:22:23**

[If main cause of death is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:33:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 31 Mar 2021 18:21:39 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:26:21 |

US3342046

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:22:23**

[Date of death \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:33:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 31 Mar 2021 18:21:39 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:26:21 |



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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:22:23**

[Was autopsy performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 12:33:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 31 Mar 2021 18:21:39 |
| User signature succeeded. | Paul Pickrell (b) (4)  | 12 Mar 2021 23:15:11 |
| User entered empty.       | Eileen Euperio (b) (4) | 14 Jan 2021 16:26:21 |

**US3342046**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:23**

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                             | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered<br>'USA-US203-2020-MRNA-1273-P301000008' | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Paul'       | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Pickrell'   | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [Street](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address:](#) City

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [State](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address: Postal Code](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 15 Jan 2021 17:40:03 |
| User entered 'US'         | System                      | 01 Dec 2020 17:52:49 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '4'  | System           | 12 Mar 2021 14:36:46 |
| User entered '3'  | System           | 09 Feb 2021 22:28:48 |
| User entered '2'  | System           | 15 Jan 2021 17:40:16 |
| User entered '1'  | System           | 01 Dec 2020 17:52:49 |

**US3342046**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:23**

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                             | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered<br>'USA-US203-2020-MRNA-1273-P301000008' | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Paul'       | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Pickrell'   | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [Street](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address:](#) City

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [State](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [Postal Code](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 15 Jan 2021 17:40:03 |
| User entered 'US'         | System                      | 01 Dec 2020 17:52:49 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '4'  | System           | 12 Mar 2021 14:36:46 |
| User entered '3'  | System           | 09 Feb 2021 22:28:48 |
| User entered '2'  | System           | 15 Jan 2021 17:40:16 |
| User entered '1'  | System           | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:22:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.        | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| User entered '01/Dec/2020 17:52' | System                      | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:22:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 15 Jan 2021 17:40:03 |
| User entered '1'          | (b) (4), (b) (6)            | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                             | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered<br>'USA-US203-2020-MRNA-1273-P301000008' | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Paul'       | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Pickrell'   | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [Street](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address:](#) City

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [State](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [Postal Code](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 15 Jan 2021 17:40:03 |
| User entered 'US'         | System                      | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '4'  | System           | 12 Mar 2021 14:36:46 |
| User entered '3'  | System           | 09 Feb 2021 22:28:48 |
| User entered '2'  | System           | 15 Jan 2021 17:40:16 |
| User entered '1'  | System           | 01 Dec 2020 17:52:49 |

**US3342046**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:22:23**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.        | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| User entered '15/Jan/2021 12:40' | System                      | 15 Jan 2021 17:40:16 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:22:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)      | 09 Feb 2021 22:28:56 |
| User entered '1'          | (b) (4), (b) (6)      | 15 Jan 2021 17:40:16 |

**US3342046**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:23**

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                             | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered<br>'USA-US203-2020-MRNA-1273-P301000008' | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Paul'       | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Pickrell'   | System                      | 09 Feb 2021 22:28:48 |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address: Street](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [City](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address:](#) [State](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [Postal Code](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 15 Jan 2021 17:40:03 |
| User entered 'US'         | System                      | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '4'  | System           | 12 Mar 2021 14:36:46 |
| User entered '3'  | System           | 09 Feb 2021 22:28:48 |
| User entered '2'  | System           | 15 Jan 2021 17:40:16 |
| User entered '1'  | System           | 01 Dec 2020 17:52:49 |

**US3342046**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:22:23**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.        | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| User entered '09/Feb/2021 17:28' | System                      | 09 Feb 2021 22:28:48 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:22:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered '1'          | (b) (4), (b) (6)            | 09 Feb 2021 22:28:48 |

**US3342046**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:22:23**

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded.                             | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered<br>'USA-US203-2020-MRNA-1273-P301000008' | System                      | 01 Dec 2020 17:51:33 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 01 Dec 2020 17:52:40 |
| User entered 'No (N)'     | System                      | 01 Dec 2020 17:51:33 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Paul'       | System                      | 09 Feb 2021 22:28:48 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Feb 2021 22:28:56 |
| User entered 'Pickrell'   | System                      | 09 Feb 2021 22:28:48 |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

**Site Address:** [Street](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [City](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

Site Address: [State](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

**Folder:** SAE USA-US203-2020-MRNA-1273-P301000008

**Form:** Safety Report Form

**Generated On:** 11 Aug 2021 22:22:23

[Site Address: Postal Code](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
|                   |                  |                      |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 00:45:04 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 15 Jan 2021 17:40:03 |
| User entered 'US'         | System                      | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 11 Aug 2021 22:22:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 14:05:09 |
| User entered '4'  | System           | 12 Mar 2021 14:36:46 |
| User entered '3'  | System           | 09 Feb 2021 22:28:48 |
| User entered '2'  | System           | 15 Jan 2021 17:40:16 |
| User entered '1'  | System           | 01 Dec 2020 17:52:49 |

US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:22:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 02 May 2021 14:05:09 |
| DataPoint Verified.              | (b) (4), (b) (6)      | 16 Apr 2021 18:12:43 |
| User signature succeeded.        | Paul Pickrell (b) (4) | 12 Mar 2021 23:15:11 |
| User entered '12/Mar/2021 08:36' | (b) (4)<br>System     | 12 Mar 2021 14:36:46 |



US3342046

Folder: SAE USA-US203-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:22:23

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 14:05:09 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 16 Apr 2021 18:12:43 |
| User signature succeeded. | Paul Pickrell (b) (4)       | 12 Mar 2021 23:15:11 |
| User entered '1'          | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 14:36:46 |