

US3572167 (Prod: Laguna Clinical Research Associates)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:37:46

All time stamps listed in this document are displayed in GMT

US3572167

**Form: Participant Creation**

**Data signed:** (b) (4) 03 Nov 2020 06:05:18

**Generated On:** 26 Nov 2020 09:37:46

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[Participant ID](#)

US3572167

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

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US3572167

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 03 Nov 2020 06:05:18

Generated On: 26 Nov 2020 09:37:46

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 02 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1977                                                                                                                                                               |
| Age                                       | 43                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 43                                                                                                                                                                         |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input checked="" type="radio"/><br>Not Hispanic or Latino <input 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) 03 Nov 2020 06:05:16

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 03 Nov 2020 06:05:16

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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) 03 Nov 2020 06:05:16

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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) 03 Nov 2020 06:05:16

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|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | AUTISM                                                           |
| Start date (dd MMM yyyy)                                | 02 OCT 2005                                                      |
| 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)                          | OCT 2005                                                         |
| Start Year (derived)                                    | 2005                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 03 Nov 2020 06:05:16

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|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | HYPOTHYROIDISM                                                   |
| Start date (dd MMM yyyy)                                | 2 AUG 1990                                                       |
| 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)                          | AUG 1990                                                         |
| Start Year (derived)                                    | 1990                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 03 Nov 2020 06:05:16

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|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | VITAMIN D DEFICIENCY                                             |
| Start date (dd MMM yyyy)                                | 01 AUG 1990                                                      |
| 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)                          | AUG 1990                                                         |
| Start Year (derived)                                    | 1990                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 03 Nov 2020 06:05:16

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|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | HYPERTENSION                                                     |
| Start date (dd MMM yyyy)                                | 01 AUG 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)                          | AUG 1980                                                         |
| Start Year (derived)                                    | 1980                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:46

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 2 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:20 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 2 SEP 2020 11:20                     |
| Height ( <i>xxx.x</i> )                   | 70 in                                |
| Weight ( <i>xxx.x</i> )                   | 316 lb                               |
| BMI ( <i>xxx.x</i> )                      | 45.43608 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) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 03 Nov 2020 06:05:17

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 03 Nov 2020 06:05:17

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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) 03 Nov 2020 06:05:18

Generated On: 26 Nov 2020 09:37:46

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 2 SEP 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT1                                  |



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 110761

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 2 SEP 2020                                                                                             |
| Time of assessment (00:00-23:59)    | 11:20 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 2 SEP 2020 11:20                                                                                       |
| Temperature (xxx.x)                 | 98.4 F                                                                                                 |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL                                                                                               |
| Pulse (xxx)                         | 74 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 181 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 108 mmHg                                                                                               |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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)    | 2 SEP 2020                                                                                             |
| Time of assessment (00:00-23:59)    | 12:10 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 2 SEP 2020 12:10                                                                                       |
| Temperature (xxx.x)                 | 97.7 F                                                                                                 |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL                                                                                               |
| Pulse (xxx)                         | 70 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 175 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 112 mmHg                                                                                               |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

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) 03 Nov 2020 06:05:16

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 SEP 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 11:40

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) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 2 SEP 2020                           |
| Collection time (00:00-23:59)      | 11:30 (24 HR)                        |
| Collection date and time (derived) | 2 SEP 2020 11:30                     |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 2 SEP 2020                         |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 11:32                           | 2 SEP 2020 11:32                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 02 SEP 2020 12:21

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 14:30

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 02 SEP 2020 21:11 |
| PC Open Date & Time  | 02 SEP 2020 15:25 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**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

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

03 SEP 2020 20:00

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

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**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:00

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

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**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 06:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

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**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:31

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**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

02 SEP 2020 12:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 14:30

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**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

02 SEP 2020 21:13

PC Open Date & Time

02 SEP 2020 15:25

PC Close Date & Time

03 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:04

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**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

04 SEP 2020 20:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**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

06 SEP 2020 06:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**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

06 SEP 2020 20:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**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

07 SEP 2020 20:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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

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

Yes ☒

No ☐

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

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:37

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**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 ☐

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 12:22 |
| PC Open Date & Time  | 02 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 14:30 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**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 ☐

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 21:14 |
| PC Open Date & Time  | 02 SEP 2020 15:25 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**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 ☒

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 20:05 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**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 ☒



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 20:01 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

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 ☒

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 06:46 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

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 ☒

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 20:44 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

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 ☐

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

|                      |                   |                              |
|----------------------|-------------------|------------------------------|
|                      |                   | Yes <input type="checkbox"/> |
| PC Time stamp        | 07 SEP 2020 20:13 |                              |
| PC Open Date & Time  | 07 SEP 2020 12:00 |                              |
| PC Close Date & Time | 08 SEP 2020 11:59 |                              |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

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 ☐



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 08 SEP 2020 20:38            |
| PC Open Date & Time  | 08 SEP 2020 12:00            |
| PC Close Date & Time | 09 SEP 2020 11:59            |

US3572167

Folder: Diary Dose 1 (1)

Form: Redness\_Day(8)

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

09 SEP 2020 20:36

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572167

Folder: Diary Dose 1 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

|                                                          |                                     |
|----------------------------------------------------------|-------------------------------------|
| TIMEPOINT                                                | DAY 8                               |
| Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b> | Yes <input type="checkbox"/>        |
|                                                          | No <input checked="" type="radio"/> |
| PC Time stamp                                            | 09 SEP 2020 20:37                   |
| PC Open Date & Time                                      | 09 SEP 2020 12:00                   |
| PC Close Date & Time                                     | 10 SEP 2020 11:59                   |

US3572167

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**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        | 09 SEP 2020 20:37 |
| PC Open Date & Time  | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:37:46

|                                                                                                 |                                                                  |
|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                | DAY 8                                                            |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input type="radio"/><br>Yes <input checked="" type="radio"/> |
| PC Time stamp                                                                                   | 09 SEP 2020 20:37                                                |
| PC Open Date & Time                                                                             | 09 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                            | 10 SEP 2020 11:59                                                |

US3572167

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 06:05:17

Generated On: 26 Nov 2020 09:37:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572167

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 06:05:17

Generated On: 26 Nov 2020 09:37:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments



US3572167

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 06:05:17

Generated On: 26 Nov 2020 09:37:46

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

US3572167

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Nov 2020 06:05:18

Generated On: 26 Nov 2020 09:37:46

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 01 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT2                                  |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 01 OCT 2020                               |
| Time of assessment (00:00-23:59)    | 09:40 (24 HR)                             |
| Vital Signs Date and Time (derived) | 01 OCT 2020 09:40                         |
| Temperature (xxx.x)                 | 96.8 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | TEMPORAL                                  |
| Pulse (xxx)                         | 85 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 20 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 212 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 119 mmHg                                  |
| Diastolic Blood Pressure units      | MMHG                                      |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

|                                     |                                            |
|-------------------------------------|--------------------------------------------|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 01 OCT 2020                                |
| Time of assessment (00:00-23:59)    | 11:15 (24 HR)                              |
| Vital Signs Date and Time (derived) | 01 OCT 2020 11:15                          |
| Temperature (xxx.x)                 | 97.5 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | TEMPORAL                                   |
| Pulse (xxx)                         | 66 beats/min                               |
| Pulse units                         | BPM                                        |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 206 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 116 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                       |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3572167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 10:45

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



US3572167

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

09:58 (24 HR)

Collection date and time (derived)

01 OCT 2020 09:58

US3572167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 01 OCT 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:56                           | 01 OCT 2020 09:56                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.3 °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        | 01 OCT 2020 11:21 |
| PC Open Date & Time  | 01 OCT 2020 11:05 |
| PC Close Date & Time | 01 OCT 2020 13:35 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 01 OCT 2020 14:30

PC Close Date & Time 02 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**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

02 OCT 2020 15:12

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**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

98.1 °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

04 OCT 2020 07:27

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 16:11

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 05 OCT 2020 20:21

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

06 OCT 2020 18:46

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

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**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

98.2 °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

07 OCT 2020 19:26

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 11:21

PC Open Date & Time

01 OCT 2020 11:05

PC Close Date & Time

01 OCT 2020 13:35

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 OCT 2020 14:30

PC Close Date & Time

02 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☒

No ☐

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

3

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 15:15

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**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

04 OCT 2020 07:28

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

5

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

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

Yes ☒

No ☐

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 16:12

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

6

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

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

Yes ☒

No ☐

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 20:22

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 18:47

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 19:27

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**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 ☐

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 01 OCT 2020 11:22 |
| PC Open Date & Time  | 01 OCT 2020 11:05 |
| PC Close Date & Time | 01 OCT 2020 13:35 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**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 ☐

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 14:30

PC Close Date & Time

02 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

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 ☒



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 OCT 2020 15:16 |
| PC Open Date & Time          | 02 OCT 2020 12:00 |
| PC Close Date & Time         | 03 OCT 2020 11:59 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

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 ☒

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 07:28 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**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 ☒

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 16:13 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

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 ☒

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 OCT 2020 20:22 |
| PC Open Date & Time          | 05 OCT 2020 12:00 |
| PC Close Date & Time         | 06 OCT 2020 11:59 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

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 ☒



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 OCT 2020 18:47 |
| PC Open Date & Time          | 06 OCT 2020 12:00 |
| PC Close Date & Time         | 07 OCT 2020 11:59 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

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 ☒

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 OCT 2020 19:27 |
| PC Open Date & Time          | 07 OCT 2020 12:00 |
| PC Close Date & Time         | 08 OCT 2020 11:59 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**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 08 OCT 2020 18:11

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3572167

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 26 Nov 2020 09:37:46

|                                                |                                     |
|------------------------------------------------|-------------------------------------|
| <b>TIMEPOINT</b>                               | DAY 8                               |
| Is there any <b>REDNESS AT INJECTION SITE?</b> | Yes <input type="checkbox"/>        |
|                                                | No <input checked="" type="radio"/> |
| PC Time Stamp                                  | 08 OCT 2020 18:11                   |
| PC Open Date & Time                            | 08 OCT 2020 12:00                   |
| PC Close Date & Time                           | 09 OCT 2020 11:59                   |

US3572167

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

|                                                          |                                        |
|----------------------------------------------------------|----------------------------------------|
| TIMEPOINT                                                | DAY 8                                  |
| Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b> | Yes <input type="checkbox"/>           |
|                                                          | No <input checked="" type="checkbox"/> |
| PC Time stamp                                            | 08 OCT 2020 18:11                      |
| PC Open Date & Time                                      | 08 OCT 2020 12:00                      |
| PC Close Date & Time                                     | 09 OCT 2020 11:59                      |

US3572167

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:37:46

|                                                                                                         |                                                                  |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                        | DAY 8                                                            |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="radio"/><br>Yes <input checked="" type="radio"/> |
| PC Time stamp                                                                                           | 08 OCT 2020 18:11                                                |
| PC Open Date & Time                                                                                     | 08 OCT 2020 12:00                                                |
| PC Close Date & Time                                                                                    | 09 OCT 2020 11:59                                                |

US3572167

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 06:05:17

Generated On: 26 Nov 2020 09:37:46

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



US3572167

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 06:05:17

Generated On: 26 Nov 2020 09:37:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572167

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 03 Nov 2020 06:05:17

Generated On: 26 Nov 2020 09:37:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572167

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Nov 2020 06:05:18

Generated On: 26 Nov 2020 09:37:46

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 \_\_\_\_\_

US3572167

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:46

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

US3572167

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

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.***



US3572167

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

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

|                               |                      |
|-------------------------------|----------------------|
| Collection date (dd MMM yyyy) | <input type="text"/> |
|-------------------------------|----------------------|

|                               |                      |
|-------------------------------|----------------------|
| Collection time (00:00-23:59) | <input type="text"/> |
|-------------------------------|----------------------|

|                                    |                      |
|------------------------------------|----------------------|
| Collection date and time (derived) | <input type="text"/> |
|------------------------------------|----------------------|

US3572167

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 61                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 68                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 75                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59



US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

|                                                                                                                                                                                 |                                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                                                                                                | DAY 82                                                           |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input checked="" type="radio"/><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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                  |
| Date and time of submission                                                                                                                                                     | 21 NOV 2020 12:32:56                                             |
| Patient Cloud Open Date & Time                                                                                                                                                  | 20 NOV 2020 00:01                                                |
| Patient Cloud Close Date & Time                                                                                                                                                 | 24 NOV 2020 23:59                                                |

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 89                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 96                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| 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 <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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| 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 <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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 152                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 159                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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05 FEB 2021 00:01

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09 FEB 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 166                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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16 FEB 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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26 FEB 2021 00:01

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US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 187                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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09 MAR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 194                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |



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

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

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

Date and time of submission

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16 MAR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 201                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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19 MAR 2021 00:01

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23 MAR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 208                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

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

Date and time of submission

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26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 215

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 222                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 229                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 236                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input 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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 243                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 250                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 257                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 264                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 271                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 278                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 285                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 299                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 320                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 327                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 334                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 341                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 348                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 362                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 376                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 404                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 411                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 418                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 432                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 439                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 460                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 474                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 488                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 502                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 530                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 551                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 600                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 607                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 614                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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10 MAY 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 621                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 628                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 642                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 649                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 670                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 691                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 705                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

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09 AUG 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 712                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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19 AUG 2022 00:01

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23 AUG 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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



US3572167

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

Date and time of submission

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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

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06 SEP 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 740                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

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

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

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13 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 761                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 768                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 782                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <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"/>                                               |



US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

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

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3572167

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:37:46

| TIMEPOINT                                                                                                                                                                       | DAY 796                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

US3572167

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3572167

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3572167

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572167

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:46

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3572167

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:37:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572167

Folder: Covid-19 Assessment (4)

Form: COVID-19 Contact

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

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

US3572167

Folder: Covid-19 Assessment (4)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3572167

Folder: Covid-19 Assessment 09 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                                                  |                                                    |
|--------------------------------------------------|----------------------------------------------------|
| Date of Contact                                  | 9 SEP 2020                                         |
| Time of Contact                                  | 09:25                                              |
| Date and Time of Contact (derived)               | 9 SEP 2020 09:25                                   |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="radio"/>     |
|                                                  | Clinical Visit - Unscheduled <input type="radio"/> |
|                                                  | Safety Call <input checked="" type="radio"/>       |
|                                                  | Convalescent Tele-visit <input type="radio"/>      |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input type="radio"/>                          |
|                                                  | No <input checked="" type="radio"/>                |

US3572167

Folder: Covid-19 Assessment 09 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

US3572167

Folder: Covid-19 Assessment 16 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                                                  |                                                    |
|--------------------------------------------------|----------------------------------------------------|
| Date of Contact                                  | 16 SEP 2020                                        |
| Time of Contact                                  | 13:55                                              |
| Date and Time of Contact (derived)               | 16 SEP 2020 13:55                                  |
| Type of Contact                                  | Clinic Visit - Scheduled <input type="radio"/>     |
|                                                  | Clinical Visit - Unscheduled <input type="radio"/> |
|                                                  | Safety Call <input checked="" type="radio"/>       |
|                                                  | Convalescent Tele-visit <input type="radio"/>      |
| Has the subject reported symptoms of SARS-COV-2? | Yes <input type="radio"/>                          |
|                                                  | No <input checked="" type="radio"/>                |

US3572167

Folder: Covid-19 Assessment 16 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

US3572167

Folder: Covid-19 Assessment 23 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

|                                                  |                                                                                                                                                                                                                                                  |
|--------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Contact                                  | 23 SEP 2020                                                                                                                                                                                                                                      |
| Time of Contact                                  | 09:30                                                                                                                                                                                                                                            |
| Date and Time of Contact (derived)               | 23 SEP 2020 09:30                                                                                                                                                                                                                                |
| Type of Contact                                  | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>                                                                                                                                                          |



US3572167

Folder: Covid-19 Assessment 23 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

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[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

US3572167

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3572167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:46

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | WORSENING - INCREASED BLOOD PRESSURE                                                                                                                             |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 7 SEP 2020                                                                                                                                                       |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         |                                                                                                                                                                  |
| 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"/>                                                                           |
| Number of Days in ICU                                          |                                                                                                                                                                  |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:46

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:46

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           |                                                                                                                                                                  |
| Adverse event                                                  | RASH ON BOTH LEGS - ON CALF AND SHINS BILATERAL                                                                                                                  |
| 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 type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 20 OCT 2020                                                                                                                                                      |
| Start time (00:00-23:59)                                       |                                                                                                                                                                  |
| AE start date and time (derived)                               |                                                                                                                                                                  |
| Ongoing?                                                       | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| If not Ongoing, end date (dd MMM yyyy)                         |                                                                                                                                                                  |
| 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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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:46

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 checked="" type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>                                                                         |
| Other action taken (check all that apply)                                    |                                                                                                                                                                                                                                                                                 |
| None                                                                         | True                                                                                                                                                                                                                                                                            |
| Concomitant Medication                                                       | False                                                                                                                                                                                                                                                                           |
| Concomitant Procedure                                                        | False                                                                                                                                                                                                                                                                           |
| Outcome                                                                      | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input checked="" type="radio"/><br>Recovered/Resolved <input 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                                                                    | SC50: CLINIC AWARE- PT WAS IN CLINIC FOR APPOINTMENT, PICTURES TAKEN TO SHOW MD. NO FURTHER CHANGES AT THIS TIME                                                                                                                                                                |
| 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 (7)

Generated On: 26 Nov 2020 09:37:46

|                                                                |                                                                                                                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID                                                           | USA-US091-2020-MRNA-1273-P30<br>1000002                                                                                                                          |
| Adverse event                                                  | ACCELERATED HYPERTENSION                                                                                                                                         |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" 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 type="radio"/><br>No <input checked="" type="radio"/>                                                                                                 |
| Start date (dd MMM yyyy)                                       | 27 OCT 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)                         | 30 OCT 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 type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                 |
| AE is serious due To (check all that apply)                    |                                                                                                                                                                  |
| Death                                                          | False                                                                                                                                                            |
| Life threatening                                               | False                                                                                                                                                            |
| Requires inpatient or prolongation of existing Hospitalization | True                                                                                                                                                             |
| Hospital Admission Date (dd MMM yyyy)                          | 27 OCT 2020                                                                                                                                                      |
| Hospital Discharge Date (dd MMM yyyy)                          | 30 OCT 2020                                                                                                                                                      |
| Admitted to ICU?                                               | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>                                                                |
| Number of Days in ICU                                          |                                                                                                                                                                  |
| v6.020 DTW (1102)                                              | 350 of 1893                                                                                                                                                      |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

|                                                                              |                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 <input type="radio"/><br>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                                                                    | SUBJECT HAD AN ADMISSION ON 10/27/2020. LONG HISTORY OF HYPERTENSION/MORBID OBESITY WITH SLEEP APNEA                                                                                                                                                                            |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 1                                                                                                                                                                                                                                                                               |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 0                                                                                                                                                                                                                                                                               |
| Admitted to ICU Derived (CSA Programming Field Only)                         | 0                                                                                                                                                                                                                                                                               |



US3572167

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

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

**Data signed:** (b) (4) 03 Nov 2020 06:05:16

**Generated On: 26 Nov 2020 09:37:46**

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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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US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:46

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | TENORMIN                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HTN                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose per administration              | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:46

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 8 SEP 2020                       |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | 2                                |
| Interval Dosage Unit Number (derived)                             |                          | 1                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:46

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | HYDRALAZINE                                                                                                                                                                                                                                                                                                                                                                                                              |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HTN                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose per administration        | 100                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input checked="" type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:37:46

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 22 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 30 OCT 2020                         |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | 3                                   |
| Interval Dosage Unit Number (derived)                             |                          | 1                                   |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:46

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ALEVE                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | PAIN                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 220                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:37:46

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 8 SEP 2020                       |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>             |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>             |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VITAMIN D                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | VITAMIN D DEFICIENCY                                                                                                                                                                                                                                                                                                                                                                                                     |
| Dose per administration        | 10000                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input checked="" type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | PT DID NOT STATE<br>Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                        |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 01 AUG 1990                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>             |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>             |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LEVOTHYROXIN                                                                                                                                                                                                                                                                                                                                                                                                             |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPOTHYROIDISM                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dose per administration        | 75                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input type="radio"/><br>ug <input checked="" type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 01 AUG 1990                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | 1                                |
| Interval Dosage Unit Number (derived)                             |                          | 1                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | RESPIRADAL                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | AUTISM                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Dose per administration        | 0.5                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input checked="" type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 02 OCT 2005                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | 3                                |
| Interval Dosage Unit Number (derived)                             |                          | 1                                |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LISINOPRIL                                                                                                                                                                                                                                                                                                                                                                                                               |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 5                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy)                                          |                          | 00 2020                             |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?                                                          | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 30 OCT 2020                         |
| Was this medication taken for solicited event?                    | Yes                      | <input type="checkbox"/>            |
|                                                                   | No                       | <input checked="" type="checkbox"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | 2                                   |
| Interval Dosage Unit Number (derived)                             |                          | 1                                   |
| Interval Dosage Definition (derived)                              | 802                      | <input type="checkbox"/>            |
|                                                                   | 803                      | <input type="checkbox"/>            |
|                                                                   | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | FUROSEMIDE (LASIX)                                                                                                                                                                                                                                                                                                                                                                                                       |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | MILD CONGESTIVE HEART FAILURE                                                                                                                                                                                                                                                                                                                                                                                            |
| Dose per administration        | 20                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/>                                                                                                                                                                                                                                   |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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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)                           |                          | 07 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 (9)

Generated On: 26 Nov 2020 09:37:46

|                                      |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication                   | METOPROLOL SUCC ER                                                                                                                                                                                                                                                                                                                                                                                                       |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                           | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration              | 25                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 7 NOV 2020                       |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| 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 (10)

Generated On: 26 Nov 2020 09:37:46

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | POTASSIUM CHLORIDE                                                                                                                                                                                                                                                                                                                                                                                                       |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 10                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify | MEQ                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:46

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 7 NOV 2020                       |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| 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"/> |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:46

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LEVONOX                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | DVT                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose per administration        | UNK                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                                    |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                                       |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:37:46

|                                                                   |                          |                                     |
|-------------------------------------------------------------------|--------------------------|-------------------------------------|
|                                                                   | 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"/>            |
| <hr/>                                                             |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date (dd MMM yyyy) <input type="text"/>                     |                          |                                     |
| <hr/>                                                             |                          |                                     |
| Start date completely unknown                                     |                          | True                                |
| <hr/>                                                             |                          |                                     |
| Ongoing?                                                          |                          | Yes <input type="checkbox"/>        |
|                                                                   |                          | No <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 30 OCT 2020                         |
| <hr/>                                                             |                          |                                     |
| Was this medication taken for solicited event?                    |                          | Yes <input type="checkbox"/>        |
|                                                                   |                          | No <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| <hr/>                                                             |                          |                                     |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| <hr/>                                                             |                          |                                     |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|                                                                   |                          | 803 <input type="checkbox"/>        |
|                                                                   |                          | 804 <input type="checkbox"/>        |
| <hr/>                                                             |                          |                                     |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:46

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | VALSARTAN                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | HYPERTENSION                                                                                                                                                                                                                                                                                                                                                                                                             |
| Dose per administration        | 160                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:37:46

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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"/>         |
| <hr/>                                                             |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Start date (dd MMM yyyy)                                          |                          | 30 OCT 2020                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| 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"/> |

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Data signed:** (b) (4) 03 Nov 2020 06:05:16

**Generated On: 26 Nov 2020 09:37:46**

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

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

---

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures**

**Generated On: 26 Nov 2020 09:37:46**

| Procedure/Surgery date ( <i>dd MMM<br/>yyyy</i> ) | Procedure/Surgery | Indication | If indication is Other, specify |
|---------------------------------------------------|-------------------|------------|---------------------------------|
|                                                   |                   |            |                                 |
|                                                   |                   |            |                                 |

US3572167

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

---

Date of dosing discontinuation (dd MMM yyyy)

---

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

---

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

---

US3572167

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 03 Nov 2020 06:05:16

Generated On: 26 Nov 2020 09:37:46

Date of study discontinuation/completion (dd MMM yyyy) \_\_\_\_\_

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 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 \_\_\_\_\_

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"/> |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

|                                                                |                                                                  |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                          | USA-US091-2020-MRNA-1273-P301000002                              |
| Serious                                                        | Yes <input checked="" type="radio"/><br>No <input 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 checked="" type="radio"/><br>No <input 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                                      | MILTON                                                           |
| Investigator's Last Name                                       | HABER                                                            |
| Site Address: Street                                           | 2344 LAGUNA DEL MAR, SUITE 201                                   |
| Site Address: City                                             | LAREDO                                                           |
| Site Address: State                                            | TX                                                               |
| Site Address: Postal Code                                      | 78041                                                            |
| Investigator Country                                           | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                             | 4                                                                |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:46

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US091-2020-MRNA-1273-P301000002                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | MILTON                                                           |
| Investigator's Last Name                                                                                                                                                                      | HABER                                                            |
| Site Address: Street                                                                                                                                                                          | 2344 LAGUNA DEL MAR, SUITE 201                                   |
| Site Address: City                                                                                                                                                                            | LAREDO                                                           |
| Site Address: State                                                                                                                                                                           | TX                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 78041                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 02/NOV/2020 20:33                                                |
| 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                                                             |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:46

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US091-2020-MRNA-1273-P301000002                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | MILTON                                                           |
| Investigator's Last Name                                                                                                                                                                      | HABER                                                            |
| Site Address: Street                                                                                                                                                                          | 2344 LAGUNA DEL MAR, SUITE 201                                   |
| Site Address: City                                                                                                                                                                            | LAREDO                                                           |
| Site Address: State                                                                                                                                                                           | TX                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 78041                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 04/NOV/2020 13:10                                                |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                             |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:46

|                                                                                                                                                                                               |                                                                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US091-2020-MRNA-1273-P301000002                              |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/><br>No <input 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 checked="" type="radio"/><br>No <input 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                                                                                                                                                                     | MILTON                                                           |
| Investigator's Last Name                                                                                                                                                                      | HABER                                                            |
| Site Address: Street                                                                                                                                                                          | 2344 LAGUNA DEL MAR, SUITE 201                                   |
| Site Address: City                                                                                                                                                                            | LAREDO                                                           |
| Site Address: State                                                                                                                                                                           | TX                                                               |
| Site Address: Postal Code                                                                                                                                                                     | 78041                                                            |
| Investigator Country                                                                                                                                                                          | US                                                               |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                                |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 11/NOV/2020 14:06                                                |
| 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                                                             |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:37:46

|                                                                                                                                                                                               |                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| SAEID                                                                                                                                                                                         | USA-US091-2020-MRNA-1273-P301000002                           |
| Serious                                                                                                                                                                                       | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death                                                                                                                                                                                         | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening                                                                                                                                                                              | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization                                                                                                                                | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                                                                                                                                                            | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event                                                                                                                                                               | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name                                                                                                                                                                     | MILTON                                                        |
| Investigator's Last Name                                                                                                                                                                      | HABER                                                         |
| Site Address: Street                                                                                                                                                                          | 2344 LAGUNA DEL MAR, SUITE 201                                |
| Site Address: City                                                                                                                                                                            | LAREDO                                                        |
| Site Address: State                                                                                                                                                                           | TX                                                            |
| Site Address: Postal Code                                                                                                                                                                     | 78041                                                         |
| Investigator Country                                                                                                                                                                          | US                                                            |
| E2B Transmit Flag (Derived/Hidden)                                                                                                                                                            | 4                                                             |
| Date of submission (Pre-filled from custom function)                                                                                                                                          | 19/NOV/2020 22:46                                             |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True                                                          |

Audit

US3572167 (Prod: Laguna Clinical Research Associates)

US3572167

**Form: Participant Creation**

**Generated On: 26 Nov 2020 09:37:46**

[Participant ID](#)

| Audit                     | User                                        | Time (GMT)           |
|---------------------------|---------------------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)                        | 03 Nov 2020 06:05:19 |
| User entered 'US3572167'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 16:05:12 |

US3572167

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:37:46**

[Was this visit performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 16:50:40 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:37:46**

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

| Audit                      | User                                                   | Time (GMT)           |
|----------------------------|--------------------------------------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)                                   | 03 Nov 2020 06:05:19 |
| User entered '02 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 16:05:13 |

US3572167

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:37:46**

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

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| User signature succeeded.      | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                | (b) (4)              |                      |
| User entered 'Clinic (Clinic)' | Alisha Lutat (b) (4) | 02 Sep 2020 16:50:40 |
|                                | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:37:46**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 02 Sep 2020 16:50:40 |



US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User                                                   | Time (GMT)           |
|----------------------------|--------------------------------------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)                                   | 03 Nov 2020 06:05:19 |
| User entered (b) (6) 1977' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 16:05:14 |

US3572167

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:37:46

[Age](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '43'         | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 02 Sep 2020 16:51:06 |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '43' | System | 02 Sep 2020 16:51:26 |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Sex](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Male (M)'   | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Ethnicity](#)

| Audit                                                  | User                 | Time (GMT)           |
|--------------------------------------------------------|----------------------|----------------------|
| User signature succeeded.                              | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                                        | (b) (4)              |                      |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                                                        | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[White](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '1'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Black](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Asian](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[American Indian or Alaska Native](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Other](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[If race is Other, specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 09:37:46**

[Not reported](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:06 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Sep 2020' | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:26 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2020' | System | 02 Sep 2020 16:51:26 |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 02 Sep 2020 16:51:26 |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[Protocol Version](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| User signature succeeded.      | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                | (b) (4)              |                      |
| User entered 'Amendment 3 (3)' | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:26 |
|                                | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[Was participant enrolled in the study?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:26 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[If No, indicate reason for screen fail](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:26 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

If reason for screen fail is Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:26 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[Was this participant screened previously?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:26 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[If Yes, previous participant number](#)

| Audit                     | User                                        | Time (GMT)           |
|---------------------------|---------------------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)                        | 03 Nov 2020 06:05:19 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 16:05:13 |



US3572167

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 09:37:46**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Sep 2020 16:51:33 |

US3572167

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 09:37:46**

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:33 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 09:37:46**

[Were any significant conditions reported?](#)

| Audit                                                                                                                                                       | User                                       | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| User opened query 'Per review of SAE reports, subject appears to have med hx of sleep apnea and DVT. Please review and if yes please add.' (Site from CRA). | (b) (4), (b) (6)                           | 12 Nov 2020 21:41:25 |
| User signature succeeded.                                                                                                                                   | Milton Haber (b) (4)                       | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'                                                                                                                                      | (b) (4)<br>Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:10:13 |

US3572167

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:37:46

[Condition](#)

| Audit                                                                                                                                                                                                 | User                            | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded.                                                                                                                                                                             | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Developmental disorders NEC, HLT: Pervasive developmental disorders NEC, PT: Autism spectrum disorder, LLT: Autism - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 02 Sep 2020 20:13:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                          | Coder Import (b) (4)<br>(b) (4) | 02 Sep 2020 20:13:50 |
| Data point term sent to Coder                                                                                                                                                                         | System                          | 02 Sep 2020 20:12:17 |
| User entered 'Autism'                                                                                                                                                                                 | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:11:57 |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '02 Oct 2005' | Alisha Lutat (b) (4) | 02 Sep 2020 20:11:57 |
|                            | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:11:57 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 20:11:57 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:11:57 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:11:57 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Oct 2005' | System | 02 Sep 2020 20:11:57 |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2005' | System | 02 Sep 2020 20:11:57 |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:11:57 |

US3572167

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:11:57 |

US3572167

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:37:46

[Condition](#)

| Audit                                                                                                                                                                                 | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded.                                                                                                                                                             | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                                                                                                                                                                       | (b) (4)              |                      |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0. | Coder Import (b) (4) | 02 Sep 2020 20:14:51 |
|                                                                                                                                                                                       | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                           | Coder Import (b) (4) | 02 Sep 2020 20:14:51 |
|                                                                                                                                                                                       | (b) (4)              |                      |
| Data point term sent to Coder                                                                                                                                                         | System               | 02 Sep 2020 20:13:18 |
| User entered 'Hypothyroidism'                                                                                                                                                         | Alisha Lutat (b) (4) | 02 Sep 2020 20:12:35 |
|                                                                                                                                                                                       | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Aug 1990' | Alisha Lutat (b) (4) | 02 Sep 2020 20:12:35 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:12:35 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 20:12:35 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:12:35 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:12:35 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 1990' | System | 02 Sep 2020 20:12:35 |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1990' | System | 02 Sep 2020 20:12:35 |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:12:35 |

US3572167

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:12:35 |

US3572167

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:37:46

[Condition](#)

| Audit                                                                                                                                                                                                                              | User                 | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded.                                                                                                                                                                                                          | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                                                                                                                                                                                                                    | (b) (4)              |                      |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0. | Coder Import (b) (4) | 02 Sep 2020 20:15:54 |
|                                                                                                                                                                                                                                    | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                        | Coder Import (b) (4) | 02 Sep 2020 20:15:54 |
|                                                                                                                                                                                                                                    | (b) (4)              |                      |
| Data point term sent to Coder                                                                                                                                                                                                      | System               | 02 Sep 2020 20:14:24 |
| User entered 'Vitamin D Deficiency'                                                                                                                                                                                                | Alisha Lutat (b) (4) | 02 Sep 2020 20:13:34 |
|                                                                                                                                                                                                                                    | (b) (4)              |                      |



US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '01 Aug 1990' | Alisha Lutat (b) (4) | 02 Sep 2020 20:13:34 |
|                            | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:13:34 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 20:13:34 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:13:34 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:13:34 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 1990' | System | 02 Sep 2020 20:13:34 |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1990' | System | 02 Sep 2020 20:13:34 |

US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:13:34 |



US3572167

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:13:34 |

US3572167

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:37:46

[Condition](#)

| Audit                                                                                                                                                                                          | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded.                                                                                                                                                                      | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 02 Sep 2020 20:15:55 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                   | Coder Import (b) (4)<br>(b) (4) | 02 Sep 2020 20:15:55 |
| Data point term sent to Coder                                                                                                                                                                  | System                          | 02 Sep 2020 20:14:24 |
| User entered 'Hypertension'                                                                                                                                                                    | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:14:02 |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '01 Aug 1980' | Alisha Lutat (b) (4) | 02 Sep 2020 20:14:02 |
|                            | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:14:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 20:14:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:14:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:14:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Month and Year \(derived\)](#)

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 1980' | System | 02 Sep 2020 20:14:02 |



US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Start Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1980' | System | 02 Sep 2020 20:14:02 |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Month and Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:14:02 |

US3572167

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Stop Year \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 02 Sep 2020 20:14:02 |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Were vital signs assessed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Sep 2020' | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '11:20'      | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 11:20' | System | 02 Sep 2020 20:15:11 |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Height \(xxx.x\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '70' in      | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |
| DataPoint set to visible. | System               | 02 Sep 2020 16:51:33 |



US3572167

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:46

[Weight \(xxx.x\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '316' lb     | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |
| DataPoint set to visible. | System               | 02 Sep 2020 16:51:33 |

US3572167

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:37:46

BMI (xxx.x)

| Audit                                                                                                                                                                                                                     | User                 | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).                                                           | (b) (4), (b) (6)     | 03 Sep 2020 18:29:41 |
| Query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' answered with 'Protocol deviation noted; pt stratified incorrectly. ' (Site from System). | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:36 |
| User opened query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).                                                           | System               | 02 Sep 2020 20:15:11 |
| User entered '45.43608'                                                                                                                                                                                                   | System               | 02 Sep 2020 20:15:11 |
| DataPoint set to visible.                                                                                                                                                                                                 | System               | 02 Sep 2020 16:51:33 |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 02 Sep 2020 20:15:11 |
| DataPoint set to visible. | System | 02 Sep 2020 16:51:33 |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Temperature \(xxx.x\)](#)

| Audit                                    | User                 | Time (GMT)           |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)              |                      |
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                                          | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Route of measurement](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[If Other, specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Pulse \(xxx\)](#)

| Audit                                    | User                 | Time (GMT)           |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)              |                      |
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                                          | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 02 Sep 2020 20:15:11 |



US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate \(xxx\)](#)

| Audit                                    | User                 | Time (GMT)           |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)              |                      |
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                                          | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 02 Sep 2020 20:15:11 |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                                    | User                 | Time (GMT)           |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)              |                      |
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                                          | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:15:11 |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                    | User                 | Time (GMT)           |
|------------------------------------------|----------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)              |                      |
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:11 |
|                                          | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:15:11 |

US3572167

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:37:46**

[Was the physical examination performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:48 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:37:46**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Sep 2020' | Alisha Lutat (b) (4) | 02 Sep 2020 20:15:48 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |

US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |



US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Other**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

[Specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

No Risk Identified

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder:** Screening

**Form:** Risk of Exposure

**Generated On:** 26 Nov 2020 09:37:46

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered '0'          | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |



US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Resides in a single family home** (i.e., detached housing)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '1'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 09:37:46**

**Other**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '0'          | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:37:46

[Specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 20:17:03 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:46

[Was this visit performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:49 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:46

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Sep 2020' | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:49 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:37:46

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| User signature succeeded.      | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                | (b) (4)              |                      |
| User entered 'Clinic (Clinic)' | Alisha Lutat (b) (4) | 02 Sep 2020 16:51:49 |
|                                | (b) (4)              |                      |



US3572167

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:37:46**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 02 Sep 2020 16:51:49 |

US3572167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

What was the date of randomization? (dd MMM yyyy)

| Audit                      | User                                                   | Time (GMT)           |
|----------------------------|--------------------------------------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)                                   | 03 Nov 2020 06:05:19 |
| User entered '02 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 16:15:12 |

US3572167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

[What was the participant's randomization number?](#)

| Audit                     | User                                        | Time (GMT)           |
|---------------------------|---------------------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)                        | 03 Nov 2020 06:05:19 |
| User entered '110761'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 16:15:12 |

US3572167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

[In what Cohort was the participant enrolled?](#)

| Audit                                                 | User                                        | Time (GMT)           |
|-------------------------------------------------------|---------------------------------------------|----------------------|
| User signature succeeded.                             | Milton Haber (b) (4)                        | 03 Nov 2020 06:05:19 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Sep 2020 16:15:12 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:37:46**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)            | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>Alisha Lutat (b) (4) | 02 Sep 2020 16:52:14 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:37:46**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:14 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

Severe obesity (body mass index > or = 40kg/m2

| Audit                                                                                                                                              | User                                       | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|
| User opened query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile ' (Site from DM). | (b) (4), (b) (6)                           | 20 Nov 2020 20:14:20 |
| User signature succeeded.                                                                                                                          | Milton Haber (b) (4)                       | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'                                                                                                                              | (b) (4)<br>Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 16:52:14 |

US3572167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:14 |
|                           | (b) (4)              |                      |



US3572167

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:37:46

[Liver Disease](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:14 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 09:37:46**

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit                                        | User                 | Time (GMT)           |
|----------------------------------------------|----------------------|----------------------|
| User entered 'No (N)'                        | Alisha Lutat (b) (4) | 10 Nov 2020 16:24:10 |
| Amendment Manager: DataPoint set to visible. | (b) (4)              | 19 Sep 2020 04:54:12 |
| Amendment Manager inserted this DataPoint.   | System               | 19 Sep 2020 04:54:10 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

Height

| Audit                                    | User                            | Time (GMT)           |
|------------------------------------------|---------------------------------|----------------------|
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

Weight

| Audit                                    | User                            | Time (GMT)           |
|------------------------------------------|---------------------------------|----------------------|
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

Height

| Audit                                    | User                            | Time (GMT)           |
|------------------------------------------|---------------------------------|----------------------|
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

Weight

| Audit                                    | User                            | Time (GMT)           |
|------------------------------------------|---------------------------------|----------------------|
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

[Timepoint](#)

| Audit                                            | User                            | Time (GMT)           |
|--------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Were vital signs assessed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |



US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '2 Sep 2020' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '11:20' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 11:20' | System | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

Temperature (xxx.x)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered '98.4' F | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of measurement](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User entered 'Other (Other)' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[If Other, specify](#)

| Audit                   | User                            | Time (GMT)           |
|-------------------------|---------------------------------|----------------------|
| User entered 'temporal' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

[Pulse \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '74' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 02 Sep 2020 20:26:59 |



US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '18' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

Systolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                                              | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).             | System                          | 17 Sep 2020 00:25:49 |
| Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System                          | 17 Sep 2020 00:25:49 |
| Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."                             | System                          | 17 Sep 2020 00:25:48 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                | System                          | 02 Sep 2020 20:26:59 |
| User entered '181'                                                                                                                                                                                                                 | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

Diastolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                        | User                            | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                          | System                          | 17 Sep 2020 00:25:48 |
| User opened 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). | System                          | 02 Sep 2020 20:26:59 |
| User entered '108'                                                                                                                                                                           | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

Height

| Audit                                    | User                            | Time (GMT)           |
|------------------------------------------|---------------------------------|----------------------|
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:37:46

Weight

| Audit                                    | User                            | Time (GMT)           |
|------------------------------------------|---------------------------------|----------------------|
| User entered missing code ND - Not Done. | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |



US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

[Timepoint](#)

| Audit                                              | User                            | Time (GMT)           |
|----------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Were vital signs assessed?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User entered '2 Sep 2020' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User                            | Time (GMT)           |
|----------------------|---------------------------------|----------------------|
| User entered '12:10' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 12:10' | System | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

Temperature (xxx.x)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered '97.7' F | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of measurement](#)

| Audit                        | User                            | Time (GMT)           |
|------------------------------|---------------------------------|----------------------|
| User entered 'Other (Other)' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[If Other, specify](#)

| Audit                   | User                            | Time (GMT)           |
|-------------------------|---------------------------------|----------------------|
| User entered 'temporal' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |



US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

[Pulse \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '70' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate \(xxx\)](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '18' | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

Systolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                                              | User                            | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).             | System                          | 17 Sep 2020 00:25:49 |
| Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System                          | 17 Sep 2020 00:25:49 |
| Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."                             | System                          | 17 Sep 2020 00:25:48 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                | System                          | 02 Sep 2020 20:26:59 |
| User entered '175'                                                                                                                                                                                                                 | Alisha Lutat (b) (4)<br>(b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:26:59 |

US3572167

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

Diastolic Blood Pressure (xxx)

| Audit                                                                                                                                                                                                                                                                      | User                 | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                                                       | (b) (4), (b) (6)     | 20 Nov 2020 05:18:06 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'pt has history of hypertension. Per PI, NCS documented in source ' (Site from System). | Alisha Lutat (b) (4) | 19 Nov 2020 14:53:17 |
| Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                                    | System               | 17 Sep 2020 00:25:49 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.                                                                                                                                                        | System               | 17 Sep 2020 00:25:48 |
| User opened 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).                                                                               | System               | 02 Sep 2020 20:26:59 |
| User entered '112'                                                                                                                                                                                                                                                         | Alisha Lutat (b) (4) | 02 Sep 2020 20:26:59 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Sep 2020 20:26:59 |



US3572167

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:46

[Was the physical examination performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 09 Sep 2020 14:49:23 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:37:46

Date of examination (dd MMM yyyy)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 09 Sep 2020 14:49:23 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[Was study treatment given?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:42 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[If No, reason not given](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:42 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:42 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Sep 2020' | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:42 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '11:40'      | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:42 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 11:40' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[Which arm was used to give treatment?](#)

| Audit                              | User                 | Time (GMT)           |
|------------------------------------|----------------------|----------------------|
| User signature succeeded.          | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                    | (b) (4)              |                      |
| User entered 'Left Arm (LEFT ARM)' | Alisha Lutat (b) (4) | 02 Sep 2020 16:52:42 |
|                                    | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:46

[Was the sample collected?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 09 Sep 2020 14:49:45 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '2 Sep 2020' | Alisha Lutat (b) (4) | 09 Sep 2020 14:49:45 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:37:46

Collection time (00:00-23:59)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '11:30'      | Alisha Lutat (b) (4) | 09 Sep 2020 14:49:45 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 11:30' | System | 09 Sep 2020 14:49:45 |



US3572167

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:37:46**

Collection date (dd MMM yyyy)

| Audit                                                                                                                                   | User                 | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User signature succeeded.                                                                                                               | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | (b) (4)              | 09 Sep 2020 14:50:21 |
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). | System               | 09 Sep 2020 14:50:21 |
| User entered '2 Sep 2020' reason for change: Data Entry Error                                                                           | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:21 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).                    | (b) (4)              | 09 Sep 2020 14:50:02 |
| User entered '9 Sep 2020'                                                                                                               | System               | 09 Sep 2020 14:50:02 |
|                                                                                                                                         | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:02 |
|                                                                                                                                         | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Lab Test](#)

| Audit                                                        | User                            | Time (GMT)           |
|--------------------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Alisha Lutat (b) (4)<br>(b) (4) | 09 Sep 2020 14:50:02 |

US3572167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:46

[Was the sample collected?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '11:32'      | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '2 Sep 2020 11:32' | System | 09 Sep 2020 14:50:21 |
| User entered '9 Sep 2020 11:32' | System | 09 Sep 2020 14:50:02 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Lab Test](#)

| Audit                                                        | User                            | Time (GMT)           |
|--------------------------------------------------------------|---------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Alisha Lutat (b) (4)<br>(b) (4) | 09 Sep 2020 14:50:02 |

US3572167

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:46

[Was the sample collected?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:02 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:02 |
|                           | (b) (4)              |                      |



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**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 14:50:02 |

US3572167

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 09 Sep 2020 14:50:41 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 14:50:41 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:21:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5374a504-52bf-44f1-ad5a-fada11c4bfba' | System | 02 Sep 2020 17:21:46 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Sep 2020 17:21:46 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:21:35', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5374a504-52bf-44f1-ad5a-fada11c4bfba' User entered '97.7' | System | 02 Sep 2020 17:21:46 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:21:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5374a504-52bf-44f1-ad5a-fada11c4bfba' | System | 02 Sep 2020 17:21:46 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 17:21:46 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:21:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5374a504-52bf-44f1-ad5a-fada11c4bfba' | System | 02 Sep 2020 17:21:46 |
| User entered '02 Sep 2020 12:21'                                                                                                                                                                                                                               | System | 02 Sep 2020 17:21:46 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:30' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:11:19', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ebb1dfc1-db0d-4792-af48-072e7fca71ab' | System | 03 Sep 2020 02:11:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 03 Sep 2020 02:11:57 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:11:35', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ebb1dfc1-db0d-4792-af48-072e7fca71ab' User entered '97.7' | System | 03 Sep 2020 02:11:57 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:11:43', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ebb1dfc1-db0d-4792-af48-072e7fca71ab' | System | 03 Sep 2020 02:11:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 02:11:57 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:11:54', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ebb1dfc1-db0d-4792-af48-072e7fca71ab' | System | 03 Sep 2020 02:11:57 |
| User entered '02 Sep 2020 21:11'                                                                                                                                                                                                                               | System | 03 Sep 2020 02:11:57 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:25' | System | 02 Sep 2020 16:52:42 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 2' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:00:07', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3528f6f-ba3a-4725-981f-0475ead40914' | System | 04 Sep 2020 01:00:44 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Sep 2020 01:00:44 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:00:19', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3528f6f-ba3a-4725-981f-0475ead40914' | System | 04 Sep 2020 01:00:44 |
| User entered '96.7'                                                                                                                                                                                                                                            | System | 04 Sep 2020 01:00:44 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:00:29', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3528f6f-ba3a-4725-981f-0475ead40914' | System | 04 Sep 2020 01:00:44 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 01:00:44 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:00:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3528f6f-ba3a-4725-981f-0475ead40914' | System | 04 Sep 2020 01:00:44 |
| User entered '03 Sep 2020 20:00'                                                                                                                                                                                                                               | System | 04 Sep 2020 01:00:44 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |



US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 3' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:00:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3e5ebdb7-2efe-40e0-baa1-9667c98f458f' | System | 05 Sep 2020 01:00:38 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 05 Sep 2020 01:00:38 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:00:15', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3e5ebdb7-2efe-40e0-baa1-9667c98f458f' User entered '97.6' | System | 05 Sep 2020 01:00:38 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:00:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3e5ebdb7-2efe-40e0-baa1-9667c98f458f' | System | 05 Sep 2020 01:00:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Sep 2020 01:00:38 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:00:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3e5ebdb7-2efe-40e0-baa1-9667c98f458f' | System | 05 Sep 2020 01:00:38 |
| User entered '04 Sep 2020 20:00'                                                                                                                                                                                                                               | System | 05 Sep 2020 01:00:38 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 4' | System | 02 Sep 2020 16:52:42 |



US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:08', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '25147e6d-8064-4d3d-ae77-5d794383861e' | System | 06 Sep 2020 11:45:38 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Sep 2020 11:45:38 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '25147e6d-8064-4d3d-ae77-5d794383861e' User entered '97.6' | System | 06 Sep 2020 11:45:38 |
|                                                                                                                                                                                                                                                                                    | System | 06 Sep 2020 11:45:38 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '25147e6d-8064-4d3d-ae77-5d794383861e' | System | 06 Sep 2020 11:45:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 11:45:38 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:32', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '25147e6d-8064-4d3d-ae77-5d794383861e' | System | 06 Sep 2020 11:45:38 |
| User entered '06 Sep 2020 06:45'                                                                                                                                                                                                                               | System | 06 Sep 2020 11:45:38 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 5' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:05', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '918f65ae-3247-4b8b-9513-9ccf0562d63b' | System | 07 Sep 2020 01:43:23 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 07 Sep 2020 01:43:23 |



US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '918f65ae-3247-4b8b-9513-9ccf0562d63b' | System | 07 Sep 2020 01:43:23 |
| User entered '97.5'                                                                                                                                                                                                                                            | System | 07 Sep 2020 01:43:23 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '918f65ae-3247-4b8b-9513-9ccf0562d63b' | System | 07 Sep 2020 01:43:23 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 01:43:23 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:20', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '918f65ae-3247-4b8b-9513-9ccf0562d63b' | System | 07 Sep 2020 01:43:23 |
| User entered '06 Sep 2020 20:43'                                                                                                                                                                                                                               | System | 07 Sep 2020 01:43:23 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 6' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '77782c60-bd8f-4d95-9641-caa4707746ff' | System | 08 Sep 2020 01:12:36 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Sep 2020 01:12:36 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:22', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '77782c60-bd8f-4d95-9641-caa4707746ff' | System | 08 Sep 2020 01:12:36 |
| User entered '97.6'                                                                                                                                                                                                                                            | System | 08 Sep 2020 01:12:36 |



US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '77782c60-bd8f-4d95-9641-caa4707746ff' | System | 08 Sep 2020 01:12:36 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 01:12:36 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:32', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '77782c60-bd8f-4d95-9641-caa4707746ff' | System | 08 Sep 2020 01:12:36 |
| User entered '07 Sep 2020 20:12'                                                                                                                                                                                                                               | System | 08 Sep 2020 01:12:36 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 7' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:31:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '91d9647b-3a88-4845-81a8-d6cfdb4535cb' User entered 'Yes (Y)' | System | 09 Sep 2020 01:31:48 |
|                                                                                                                                                                                                                                                                                       | System | 09 Sep 2020 01:31:48 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:31:35', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '91d9647b-3a88-4845-81a8-d6cfdb4535cb' User entered '98.1' | System | 09 Sep 2020 01:31:48 |
|                                                                                                                                                                                                                                                                                    | System | 09 Sep 2020 01:31:48 |

US3572167

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:31:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '91d9647b-3a88-4845-81a8-d6cfdb4535cb' | System | 09 Sep 2020 01:31:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 09 Sep 2020 01:31:48 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:31:43', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '91d9647b-3a88-4845-81a8-d6cfdb4535cb' User entered '08 Sep 2020 20:31' | System | 09 Sep 2020 01:31:48 |
|                                                                                                                                                                                                                                                                                                 | System | 09 Sep 2020 01:31:48 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:05', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '72861df3-f04a-4ae3-ace3-017441d333f6' | System | 02 Sep 2020 17:22:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:25 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:11', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '72861df3-f04a-4ae3-ace3-017441d333f6' | System | 02 Sep 2020 17:22:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 17:22:25 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '72861df3-f04a-4ae3-ace3-017441d333f6' | System | 02 Sep 2020 17:22:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 17:22:25 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:20', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '72861df3-f04a-4ae3-ace3-017441d333f6' | System | 02 Sep 2020 17:22:25 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:25 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '72861df3-f04a-4ae3-ace3-017441d333f6' User entered '02 Sep 2020 12:22' | System | 02 Sep 2020 17:22:25 |
|                                                                                                                                                                                                                                                                                                 | System | 02 Sep 2020 17:22:25 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:30' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:12:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cbb4c14a-9f73-46a8-bb47-7565bedda381' | System | 03 Sep 2020 02:13:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:13:04 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:12:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cbb4c14a-9f73-46a8-bb47-7565bedda381' | System | 03 Sep 2020 02:13:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 02:13:04 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:12:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cbb4c14a-9f73-46a8-bb47-7565bedda381' | System | 03 Sep 2020 02:13:04 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 02:13:04 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:12:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cbb4c14a-9f73-46a8-bb47-7565bedda381' | System | 03 Sep 2020 02:13:04 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:13:04 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:13:01', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cbb4c14a-9f73-46a8-bb47-7565bedda381' | System | 03 Sep 2020 02:13:04 |
| User entered '02 Sep 2020 21:13'                                                                                                                                                                                                                               | System | 03 Sep 2020 02:13:04 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:25' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 2' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:01:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9a551f87-8ffc-4ae9-b68b-9a5beb981e4b' | System | 04 Sep 2020 01:04:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:04:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:03:59', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9a551f87-8ffc-4ae9-b68b-9a5beb981e4b' | System | 04 Sep 2020 01:04:56 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Sep 2020 01:04:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:04:14', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9a551f87-8ffc-4ae9-b68b-9a5beb981e4b' User entered '5' | System | 04 Sep 2020 01:04:56 |
|                                                                                                                                                                                                                                                                                 | System | 04 Sep 2020 01:04:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:04:19', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9a551f87-8ffc-4ae9-b68b-9a5beb981e4b' | System | 04 Sep 2020 01:04:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 01:04:56 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:04:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9a551f87-8ffc-4ae9-b68b-9a5beb981e4b' | System | 04 Sep 2020 01:04:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:04:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:04:53', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9a551f87-8ffc-4ae9-b68b-9a5beb981e4b' | System | 04 Sep 2020 01:04:56 |
| User entered '03 Sep 2020 20:04'                                                                                                                                                                                                                               | System | 04 Sep 2020 01:04:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 3' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:00:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '6dfef128-2b20-4fe1-a131-ca7b0f1a5291' | System | 05 Sep 2020 01:01:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:15 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

Is there any **REDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:00:48', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '6dfef128-2b20-4fe1-a131-ca7b0f1a5291' | System | 05 Sep 2020 01:01:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Sep 2020 01:01:15 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:02', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '6dfef128-2b20-4fe1-a131-ca7b0f1a5291' | System | 05 Sep 2020 01:01:15 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Sep 2020 01:01:15 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '6dfef128-2b20-4fe1-a131-ca7b0f1a5291' | System | 05 Sep 2020 01:01:15 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:15 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:13', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '6dfef128-2b20-4fe1-a131-ca7b0f1a5291' | System | 05 Sep 2020 01:01:15 |
| User entered '04 Sep 2020 20:01'                                                                                                                                                                                                                               | System | 05 Sep 2020 01:01:15 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 4' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:39', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '28a2ba0a-b045-4758-82da-62be98d8ab40' | System | 06 Sep 2020 11:46:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:08 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:48', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '28a2ba0a-b045-4758-82da-62be98d8ab40' | System | 06 Sep 2020 11:46:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 11:46:08 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:51', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '28a2ba0a-b045-4758-82da-62be98d8ab40' | System | 06 Sep 2020 11:46:08 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 11:46:08 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '28a2ba0a-b045-4758-82da-62be98d8ab40' | System | 06 Sep 2020 11:46:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:08 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:45:59', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '28a2ba0a-b045-4758-82da-62be98d8ab40' | System | 06 Sep 2020 11:46:08 |
| User entered '06 Sep 2020 06:45'                                                                                                                                                                                                                               | System | 06 Sep 2020 11:46:08 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 5' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8397a9b5-9faa-4cf6-b71b-e2904befccea' User entered 'None (1)' | System | 07 Sep 2020 01:43:54 |
|                                                                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:43:54 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

Is there any **REDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:37', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8397a9b5-9faa-4cf6-b71b-e2904befccea' | System | 07 Sep 2020 01:43:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 01:43:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:41', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8397a9b5-9faa-4cf6-b71b-e2904befccea' | System | 07 Sep 2020 01:43:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 01:43:54 |



US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8397a9b5-9faa-4cf6-b71b-e2904befccea' User entered 'None (1)' | System | 07 Sep 2020 01:43:54 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:43:50', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8397a9b5-9faa-4cf6-b71b-e2904befccea' User entered '06 Sep 2020 20:43' | System | 07 Sep 2020 01:43:54 |
|                                                                                                                                                                                                                                                                                                 | System | 07 Sep 2020 01:43:54 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 6' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cad392e0-3645-4f40-b153-c0259b740e12' | System | 08 Sep 2020 01:12:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:12:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:43', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cad392e0-3645-4f40-b153-c0259b740e12' | System | 08 Sep 2020 01:12:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 01:12:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cad392e0-3645-4f40-b153-c0259b740e12' | System | 08 Sep 2020 01:12:56 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Sep 2020 01:12:56 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:51', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cad392e0-3645-4f40-b153-c0259b740e12' | System | 08 Sep 2020 01:12:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:12:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:54', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cad392e0-3645-4f40-b153-c0259b740e12' | System | 08 Sep 2020 01:12:56 |
| User entered '07 Sep 2020 20:12'                                                                                                                                                                                                                               | System | 08 Sep 2020 01:12:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 7' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:33:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' | System | 09 Sep 2020 01:37:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

Is there any **REDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:33:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' | System | 09 Sep 2020 01:37:56 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

| Audit                                                                                                                                                                                                                                                                            | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:36:32', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' User entered '50' | System | 09 Sep 2020 01:37:56 |
|                                                                                                                                                                                                                                                                                  | System | 09 Sep 2020 01:37:56 |



US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:37:08', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' | System | 09 Sep 2020 01:37:56 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 09 Sep 2020 01:37:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                            | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:37:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' User entered '50' | System | 09 Sep 2020 01:37:56 |
|                                                                                                                                                                                                                                                                                  | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:35:03', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' | System | 09 Sep 2020 01:37:56 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:37:54', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '76d63d01-1b38-4e9f-96c9-9af517fde409' | System | 09 Sep 2020 01:37:56 |
| User entered '08 Sep 2020 20:37'                                                                                                                                                                                                                               | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' | System | 02 Sep 2020 17:22:55 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:55 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' | System | 02 Sep 2020 17:22:55 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:55 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:38', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' | System | 02 Sep 2020 17:22:55 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:55 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' | System | 02 Sep 2020 17:22:55 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:55 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' | System | 02 Sep 2020 17:22:55 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:55 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

CHILLS

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:46', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' User entered 'None (0)' | System | 02 Sep 2020 17:22:55 |
|                                                                                                                                                                                                                                                                                        | System | 02 Sep 2020 17:22:55 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:49', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' | System | 02 Sep 2020 17:22:55 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 17:22:55 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T12:22:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ae54ab2f-b8c8-4950-9747-204ee0388ec9' User entered '02 Sep 2020 12:22' | System | 02 Sep 2020 17:22:55 |
|                                                                                                                                                                                                                                                                                                 | System | 02 Sep 2020 17:22:55 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 14:30' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:08', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:14:47 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:13', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:14:47 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:14:47 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:22', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' User entered 'None (0)' | System | 03 Sep 2020 02:14:47 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:25', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:14:47 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 03 Sep 2020 02:14:47 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:39', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 03 Sep 2020 02:14:47 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-02T21:14:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '32f56977-3b28-43ae-b43d-60ea53ad4648' | System | 03 Sep 2020 02:14:47 |
| User entered '02 Sep 2020 21:14'                                                                                                                                                                                                                               | System | 03 Sep 2020 02:14:47 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 15:25' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 2' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:03', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:06:00 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:06:00 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:06:00 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:24', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:06:00 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:38', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:06:00 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 01:06:00 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 01:06:00 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-03T20:05:59', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '90184357-09a3-4529-8e4a-9b7844ff01c2' | System | 04 Sep 2020 01:06:00 |
| User entered '03 Sep 2020 20:05'                                                                                                                                                                                                                               | System | 04 Sep 2020 01:06:00 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 3' | System | 02 Sep 2020 16:52:42 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:21', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:38', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:42', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:46', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:53', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Sep 2020 01:01:59 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-04T20:01:57', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1bd1efe6-c02a-4f16-bf16-e3e78dd73668' | System | 05 Sep 2020 01:01:59 |
| User entered '04 Sep 2020 20:01'                                                                                                                                                                                                                               | System | 05 Sep 2020 01:01:59 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 4' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:05', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:21', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:54 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:29', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Sep 2020 11:46:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:38', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' | System | 06 Sep 2020 11:46:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Sep 2020 11:46:54 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T06:46:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b758081a-7b2b-42d4-a115-c2f528b6df1e' User entered '06 Sep 2020 06:46' | System | 06 Sep 2020 11:46:54 |
|                                                                                                                                                                                                                                                                                                 | System | 06 Sep 2020 11:46:54 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 5' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:00', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:44:28 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:03', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:44:28 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:07', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:44:28 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:10', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:44:28 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:44:28 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 07 Sep 2020 01:44:28 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 07 Sep 2020 01:44:28 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-06T20:44:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'df1c5632-64c8-46c1-b200-d9fbe6a35e22' | System | 07 Sep 2020 01:44:28 |
| User entered '06 Sep 2020 20:44'                                                                                                                                                                                                                               | System | 07 Sep 2020 01:44:28 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 6' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:12:59', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:13:32 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:03', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:13:32 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:06', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:13:32 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:13:32 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:13:32 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:15', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' User entered 'None (0)' | System | 08 Sep 2020 01:13:32 |
|                                                                                                                                                                                                                                                                                        | System | 08 Sep 2020 01:13:32 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:25', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Sep 2020 01:13:32 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-07T20:13:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '710e8d9e-e24f-4d15-b685-ca3579617c29' | System | 08 Sep 2020 01:13:32 |
| User entered '07 Sep 2020 20:13'                                                                                                                                                                                                                               | System | 08 Sep 2020 01:13:32 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 16:52:42 |
| User entered 'Day 7' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:13', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 09 Sep 2020 01:39:01 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:39:01 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:26', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:39:01 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:29', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:39:01 |



US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:39:01 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:36', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 09 Sep 2020 01:39:01 |

US3572167

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 09 Sep 2020 01:39:01 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-08T20:38:59', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '80d6f7c8-d98b-4319-9ca1-eb71c8f06b7f' | System | 09 Sep 2020 01:39:01 |
| User entered '08 Sep 2020 20:38'                                                                                                                                                                                                                               | System | 09 Sep 2020 01:39:01 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 16:52:42 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 16:52:42 |

US3572167

Folder: Diary Dose 1 (1)

Form: Redness\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 09 Sep 2020 01:37:56 |
| User entered 'Day 8' | System | 09 Sep 2020 01:37:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Redness\_Day(8)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:36:49', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'c6f17c31-5767-4a55-a76e-3503aa732879' | System | 10 Sep 2020 01:37:02 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 10 Sep 2020 01:37:02 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Redness\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:36:58', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'c6f17c31-5767-4a55-a76e-3503aa732879' User entered '09 Sep 2020 20:36' | System | 10 Sep 2020 01:37:02 |
|                                                                                                                                                                                                                                                                                                 | System | 10 Sep 2020 01:37:02 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Redness\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Redness\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 01:37:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 09 Sep 2020 01:37:56 |
| User entered 'Day 8' | System | 09 Sep 2020 01:37:56 |

US3572167

Folder: Diary Dose 1 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:37:05', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '65943f37-e0a8-47d6-a260-ce31da921de6' | System | 10 Sep 2020 01:37:10 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 10 Sep 2020 01:37:10 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:37:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '65943f37-e0a8-47d6-a260-ce31da921de6' | System | 10 Sep 2020 01:37:10 |
| User entered '09 Sep 2020 20:37'                                                                                                                                                                                                                               | System | 10 Sep 2020 01:37:10 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 01:37:56 |



US3572167

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 09 Sep 2020 01:39:01 |
| User entered 'Day 8' | System | 09 Sep 2020 01:39:01 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

Select one response below to indicate the intensity of your **HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:37:15', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b0028739-205f-4d07-bb32-d2858091a769' | System | 10 Sep 2020 01:37:23 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 10 Sep 2020 01:37:23 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:37:19', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b0028739-205f-4d07-bb32-d2858091a769' | System | 10 Sep 2020 01:37:23 |
| User entered '09 Sep 2020 20:37'                                                                                                                                                                                                                               | System | 10 Sep 2020 01:37:23 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 01:39:01 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 01:39:01 |

US3572167

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 09 Sep 2020 01:37:56 |
| User entered 'Day 8' | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:37:35', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '901fc773-0230-45ce-ae83-aad3e4cde984' | System | 10 Sep 2020 01:37:47 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 10 Sep 2020 01:37:47 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-09-09T20:37:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '901fc773-0230-45ce-ae83-aad3e4cde984' | System | 10 Sep 2020 01:37:47 |
| User entered '09 Sep 2020 20:37'                                                                                                                                                                                                                               | System | 10 Sep 2020 01:37:47 |



US3572167

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Sep 2020 12:00' | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '10 Sep 2020 11:59' | System | 09 Sep 2020 01:37:56 |

US3572167

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 15:23:45 |

US3572167

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered '9 Sep 2020' | Jackie Ziegler (b) (4) | 09 Sep 2020 15:23:45 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                         | Time (GMT)           |
|--------------------------------------------|----------------------------------------------|----------------------|
| User signature succeeded.                  | Milton Haber (b) (4)                         | 03 Nov 2020 06:05:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 15:23:45 |

US3572167

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered empty.       | Jackie Ziegler (b) (4) | 09 Sep 2020 15:23:45 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 15:23:51 |

US3572167

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 15:23:51 |



US3572167

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 16 Sep 2020 19:01:04 |

US3572167

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                            | (b) (4)                |                      |
| User entered '16 Sep 2020' | Jackie Ziegler (b) (4) | 16 Sep 2020 19:01:04 |
|                            | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                         | Time (GMT)           |
|--------------------------------------------|----------------------------------------------|----------------------|
| User signature succeeded.                  | Milton Haber (b) (4)                         | 03 Nov 2020 06:05:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jackie Ziegler (b) (4)<br>(b) (4) | 16 Sep 2020 19:01:04 |

US3572167

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered empty.       | Jackie Ziegler (b) (4) | 16 Sep 2020 19:01:04 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 16 Sep 2020 19:01:10 |

US3572167

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Sep 2020 19:01:10 |

US3572167

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Sep 2020 14:32:38 |

US3572167

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                            | (b) (4)                |                      |
| User entered '23 Sep 2020' | Jackie Ziegler (b) (4) | 23 Sep 2020 14:32:38 |
|                            | (b) (4)                |                      |



US3572167

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                         | Time (GMT)           |
|--------------------------------------------|----------------------------------------------|----------------------|
| User signature succeeded.                  | Milton Haber (b) (4)                         | 03 Nov 2020 06:05:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jackie Ziegler (b) (4)<br>(b) (4) | 23 Sep 2020 14:32:38 |

US3572167

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered empty.       | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Sep 2020 14:32:38 |

US3572167

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Sep 2020 14:32:45 |

US3572167

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Sep 2020 14:32:45 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:46

[Was this visit performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 05 Oct 2020 18:04:06 |
|                           |                      |                      |

US3572167

**Folder:** Visit 2 Day 29 (1)

**Form:** Visit Date

**Generated On:** 26 Nov 2020 09:37:46

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '01 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:04:06 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:37:46

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:04:06 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 09:37:46**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 05 Oct 2020 18:04:06 |



US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

[Timepoint](#)

| Audit                                            | User             | Time (GMT)           |
|--------------------------------------------------|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                                                  |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                        |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '01 Oct 2020' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                            |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '09:40' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                      |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 09:40' | System | 05 Oct 2020 18:06:51 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

Temperature (xxx.x)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered '96.8' F | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                       |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of measurement](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Other (Other)' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                              |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[If Other, specify](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| User entered 'Temporal' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                         |                  |                      |



US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

[Pulse \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '85' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                   |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 05 Oct 2020 18:06:51 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

[Respiratory Rate \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '20' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                   |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 05 Oct 2020 18:06:51 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:37:46

[Systolic Blood Pressure \(xxx\)](#)

| Audit                                                                                                                                                                                               | User             | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System           | 05 Oct 2020 18:06:51 |
| User entered '212'                                                                                                                                                                                  | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                                                                                                                                                                       | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). |                  | 05 Oct 2020 18:06:51 |
| User entered '119'                                                                                                                                                                                          | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Oct 2020 18:06:51 |



US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

[Timepoint](#)

| Audit                                              | User             | Time (GMT)           |
|----------------------------------------------------|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

[Were vital signs assessed?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                        |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '01 Oct 2020' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                            |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Time of assessment \(00:00-23:59\)](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| User entered '11:15' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                      |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:15' | System | 05 Oct 2020 18:06:51 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

Temperature (xxx.x)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered '97.5' F | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                       |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of measurement](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Other (Other)' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                              |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[If Other, specify](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| User entered 'Temporal' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                         |                  |                      |



US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

[Pulse \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '66' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                   |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 05 Oct 2020 18:06:51 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:37:46

[Respiratory Rate \(xxx\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| User entered '18' | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |
|                   |                  |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                                                                                                                                                                                                                     | User                           | Time (GMT)                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|--------------------------------------------------|
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).<br>User entered '206' | System<br><br>(b) (4), (b) (6) | 05 Oct 2020 18:06:51<br><br>05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                                                                                                                                                                                                       | User             | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). |                  | 05 Oct 2020 18:06:51 |
| User entered '116'                                                                                                                                                                                          | (b) (4), (b) (6) | 05 Oct 2020 18:06:51 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 05 Oct 2020 18:06:51 |



US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:37:46**

[Was the physical examination performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 05 Oct 2020 18:07:42 |
|                           |                      |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 09:37:46**

[Date of examination \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '01 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:07:42 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[Was study treatment given?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | Alisha Lutat (b) (4) | 01 Oct 2020 15:47:10 |
|                           | (b) (4)              |                      |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[If No, reason not given](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 01 Oct 2020 15:47:10 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered empty.       | Alisha Lutat (b) (4) | 01 Oct 2020 15:47:10 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '1 Oct 2020' | Alisha Lutat (b) (4) | 01 Oct 2020 15:47:10 |
|                           | (b) (4)              |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '10:45'      | Alisha Lutat (b) (4) | 01 Oct 2020 15:47:10 |
|                           | (b) (4)              |                      |



US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '1 Oct 2020 10:45' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:37:46

[Which arm was used to give treatment?](#)

| Audit                              | User                 | Time (GMT)           |
|------------------------------------|----------------------|----------------------|
| User signature succeeded.          | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                                    | (b) (4)              |                      |
| User entered 'Left Arm (LEFT ARM)' | Alisha Lutat (b) (4) | 01 Oct 2020 15:47:10 |
|                                    | (b) (4)              |                      |

US3572167

**Folder:** Visit 2 Day 29 (1)

**Form:** Exposure

**Generated On:** 26 Nov 2020 09:37:46

[What was the frequency of the study treatment dosing?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 09:37:46**

[What was the route of administration for the study treatment?](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Was the sample collected?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 05 Oct 2020 18:08:33 |
|                           |                      |                      |

US3572167

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:37:46

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '01 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:08:33 |

US3572167

**Folder:** Visit 2 Day 29 (1)

**Form:** Immunogenicity Assessment

**Generated On:** 26 Nov 2020 09:37:46

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '09:58'      | (b) (4), (b) (6)     | 05 Oct 2020 18:08:33 |
|                           |                      |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 09:58' | System | 05 Oct 2020 18:08:33 |



US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '01 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:09:04 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:37:46

[Lab Test](#)

| Audit                                                        | User             | Time (GMT)           |
|--------------------------------------------------------------|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 05 Oct 2020 18:09:04 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:09:04 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered '09:56'      | (b) (4), (b) (6)     | 05 Oct 2020 18:09:04 |
|                           |                      |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 09:56' | System | 05 Oct 2020 18:09:04 |

US3572167

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:37:46

[Lab Test](#)

| Audit                                                        | User             | Time (GMT)           |
|--------------------------------------------------------------|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 05 Oct 2020 18:09:04 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:09:04 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:09:04 |



US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Collection date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 18:09:04 |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 05 Oct 2020 18:09:21 |
|                           |                      |                      |

US3572167

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:09:21 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:20:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '905a97b2-6a96-4814-952a-d1eff644fa6e' | System | 01 Oct 2020 16:21:06 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 01 Oct 2020 16:21:06 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:20:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '905a97b2-6a96-4814-952a-d1eff644fa6e' User entered '97.3' | System | 01 Oct 2020 16:21:06 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:20:57', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '905a97b2-6a96-4814-952a-d1eff644fa6e' | System | 01 Oct 2020 16:21:06 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 16:21:06 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:01', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '905a97b2-6a96-4814-952a-d1eff644fa6e' | System | 01 Oct 2020 16:21:06 |
| User entered '01 Oct 2020 11:21'                                                                                                                                                                                                                               | System | 01 Oct 2020 16:21:06 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:05' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 13:35' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 14:30' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 2' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:11:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3cb93e9b-505e-4d5a-afbd-33ef006723ec' | System | 02 Oct 2020 20:12:18 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Oct 2020 20:12:18 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:12:02', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3cb93e9b-505e-4d5a-afbd-33ef006723ec' User entered '97.5' | System | 02 Oct 2020 20:12:18 |



US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:12:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3cb93e9b-505e-4d5a-afbd-33ef006723ec' | System | 02 Oct 2020 20:12:18 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Oct 2020 20:12:18 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:12:16', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3cb93e9b-505e-4d5a-afbd-33ef006723ec' | System | 02 Oct 2020 20:12:18 |
| User entered '02 Oct 2020 15:12'                                                                                                                                                                                                                               | System | 02 Oct 2020 20:12:18 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 3' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:27:35', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '298019f5-6038-497f-b575-82cd0735fc65' | System | 04 Oct 2020 12:27:54 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Oct 2020 12:27:54 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:27:41', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '298019f5-6038-497f-b575-82cd0735fc65' | System | 04 Oct 2020 12:27:54 |
| User entered '98.1'                                                                                                                                                                                                                                            | System | 04 Oct 2020 12:27:54 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:27:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '298019f5-6038-497f-b575-82cd0735fc65' | System | 04 Oct 2020 12:27:54 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 12:27:54 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:27:50', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '298019f5-6038-497f-b575-82cd0735fc65' | System | 04 Oct 2020 12:27:54 |
| User entered '04 Oct 2020 07:27'                                                                                                                                                                                                                               | System | 04 Oct 2020 12:27:54 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 4' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:11:36', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '152dfeab-c3f2-4e74-b0a2-83169fe0fcff' | System | 04 Oct 2020 21:11:48 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 04 Oct 2020 21:11:48 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:11:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '152dfeab-c3f2-4e74-b0a2-83169fe0fcff' | System | 04 Oct 2020 21:11:48 |
| User entered '98.2'                                                                                                                                                                                                                                            | System | 04 Oct 2020 21:11:48 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:11:43', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '152dfeab-c3f2-4e74-b0a2-83169fe0fcff' | System | 04 Oct 2020 21:11:48 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 21:11:48 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:11:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '152dfeab-c3f2-4e74-b0a2-83169fe0fcff' | System | 04 Oct 2020 21:11:48 |
| User entered '04 Oct 2020 16:11'                                                                                                                                                                                                                               | System | 04 Oct 2020 21:11:48 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 5' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:21:31', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '2f21eed9-f87a-47a5-9dea-82ea5bf16a09' | System | 06 Oct 2020 01:21:49 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Oct 2020 01:21:49 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:21:37', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '2f21eed9-f87a-47a5-9dea-82ea5bf16a09' User entered '97.7' | System | 06 Oct 2020 01:21:49 |
|                                                                                                                                                                                                                                                                                    | System | 06 Oct 2020 01:21:49 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:21:41', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '2f21eed9-f87a-47a5-9dea-82ea5bf16a09' | System | 06 Oct 2020 01:21:49 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 01:21:49 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:21:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '2f21eed9-f87a-47a5-9dea-82ea5bf16a09' | System | 06 Oct 2020 01:21:49 |
| User entered '05 Oct 2020 20:21'                                                                                                                                                                                                                               | System | 06 Oct 2020 01:21:49 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 6' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:46:18', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1d708e82-9ffb-4c10-b809-9affdb2fd978' | System | 06 Oct 2020 23:46:35 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Oct 2020 23:46:35 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:46:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1d708e82-9ffb-4c10-b809-9affdb2fd978' User entered '97.7' | System | 06 Oct 2020 23:46:35 |
|                                                                                                                                                                                                                                                                                    | System | 06 Oct 2020 23:46:35 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:46:26', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1d708e82-9ffb-4c10-b809-9affdb2fd978' | System | 06 Oct 2020 23:46:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 23:46:35 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 09:37:46

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:46:32', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '1d708e82-9ffb-4c10-b809-9affdb2fd978' | System | 06 Oct 2020 23:46:35 |
| User entered '06 Oct 2020 18:46'                                                                                                                                                                                                                               | System | 06 Oct 2020 23:46:35 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |



US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 7' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Was **TEMPERATURE** taken?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:16', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8a04c975-448e-4a09-b715-07cab2850895' | System | 08 Oct 2020 00:26:33 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Oct 2020 00:26:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:21', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8a04c975-448e-4a09-b715-07cab2850895' | System | 08 Oct 2020 00:26:33 |
| User entered '98.2'                                                                                                                                                                                                                                            | System | 08 Oct 2020 00:26:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8a04c975-448e-4a09-b715-07cab2850895' | System | 08 Oct 2020 00:26:33 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Oct 2020 00:26:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:30', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '8a04c975-448e-4a09-b715-07cab2850895' | System | 08 Oct 2020 00:26:33 |
| User entered '07 Oct 2020 19:26'                                                                                                                                                                                                                               | System | 08 Oct 2020 00:26:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Oct 2020 15:47:10 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:19', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '839cb1be-eb26-4b87-9df7-cb8751249659' | System | 01 Oct 2020 16:21:38 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:21:38 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '839cb1be-eb26-4b87-9df7-cb8751249659' | System | 01 Oct 2020 16:21:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 16:21:38 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '839cb1be-eb26-4b87-9df7-cb8751249659' | System | 01 Oct 2020 16:21:38 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 16:21:38 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:32', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '839cb1be-eb26-4b87-9df7-cb8751249659' | System | 01 Oct 2020 16:21:38 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:21:38 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:35', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '839cb1be-eb26-4b87-9df7-cb8751249659' | System | 01 Oct 2020 16:21:38 |
| User entered '01 Oct 2020 11:21'                                                                                                                                                                                                                               | System | 01 Oct 2020 16:21:38 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:05' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 13:35' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Oct 2020 15:47:10 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 14:30' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 2' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:12:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' | System | 02 Oct 2020 20:15:32 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'                                                                                                                                                       | System | 02 Oct 2020 20:15:32 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:12:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' | System | 02 Oct 2020 20:15:32 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Oct 2020 20:15:32 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:14:20', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' User entered '5' | System | 02 Oct 2020 20:15:32 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:14:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' | System | 02 Oct 2020 20:15:32 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Oct 2020 20:15:32 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:14:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' User entered '3' | System | 02 Oct 2020 20:15:32 |



US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:15:25', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' | System | 02 Oct 2020 20:15:32 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'                                                                                                                                                  | System | 02 Oct 2020 20:15:32 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:15:29', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b6fe792d-d039-4a30-93ac-320f2963f6b7' | System | 02 Oct 2020 20:15:32 |
| User entered '02 Oct 2020 15:15'                                                                                                                                                                                                                               | System | 02 Oct 2020 20:15:32 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 3' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:27:58', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5b38f296-5b42-47fd-a255-b0634f871767' | System | 04 Oct 2020 12:28:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:16 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:01', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5b38f296-5b42-47fd-a255-b0634f871767' | System | 04 Oct 2020 12:28:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 12:28:16 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:06', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5b38f296-5b42-47fd-a255-b0634f871767' | System | 04 Oct 2020 12:28:16 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 12:28:16 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:11', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5b38f296-5b42-47fd-a255-b0634f871767' | System | 04 Oct 2020 12:28:16 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:16 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:14', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '5b38f296-5b42-47fd-a255-b0634f871767' | System | 04 Oct 2020 12:28:16 |
| User entered '04 Oct 2020 07:28'                                                                                                                                                                                                                               | System | 04 Oct 2020 12:28:16 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 4' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:00', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' | System | 04 Oct 2020 21:12:47 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 04 Oct 2020 21:12:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:03', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' User entered 'Yes (Y)' | System | 04 Oct 2020 21:12:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' User entered '5' | System | 04 Oct 2020 21:12:47 |



US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' User entered 'Yes (Y)' | System | 04 Oct 2020 21:12:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' User entered '4' | System | 04 Oct 2020 21:12:47 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' | System | 04 Oct 2020 21:12:47 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 21:12:47 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'e6bfdebd-8275-4f4b-a2c7-2e76a9b360ab' User entered '04 Oct 2020 16:12' | System | 04 Oct 2020 21:12:47 |
|                                                                                                                                                                                                                                                                                                 | System | 04 Oct 2020 21:12:47 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 5' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:21:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' | System | 06 Oct 2020 01:22:21 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 06 Oct 2020 01:22:21 |



US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:21:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' | System | 06 Oct 2020 01:22:21 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Oct 2020 01:22:21 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:03', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' User entered '6' | System | 06 Oct 2020 01:22:21 |
|                                                                                                                                                                                                                                                                                 | System | 06 Oct 2020 01:22:21 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:08', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' | System | 06 Oct 2020 01:22:21 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Oct 2020 01:22:21 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' User entered '4' | System | 06 Oct 2020 01:22:21 |
|                                                                                                                                                                                                                                                                                 | System | 06 Oct 2020 01:22:21 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - UNDERARM GLAND SWELLING OR TENDERNESS.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:15', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' | System | 06 Oct 2020 01:22:21 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:21 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:18', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'eee74d9f-a066-47fa-b9b8-c4447624ba38' | System | 06 Oct 2020 01:22:21 |
| User entered '05 Oct 2020 20:22'                                                                                                                                                                                                                               | System | 06 Oct 2020 01:22:21 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |



US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 6' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:46:42', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' | System | 06 Oct 2020 23:47:33 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                                                 | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:04', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' User entered 'Yes (Y)' | System | 06 Oct 2020 23:47:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:12', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' User entered '4' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' | System | 06 Oct 2020 23:47:33 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' User entered '2' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' | System | 06 Oct 2020 23:47:33 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 23:47:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:30', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '529a9f1b-4539-4a5e-8e7b-23cd8ece082d' User entered '06 Oct 2020 18:47' | System | 06 Oct 2020 23:47:33 |
|                                                                                                                                                                                                                                                                                                 | System | 06 Oct 2020 23:47:33 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 7' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:37', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' | System | 08 Oct 2020 00:27:09 |
| User entered 'Does not interfere with activity (2)'                                                                                                                                                                                                            | System | 08 Oct 2020 00:27:09 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:41', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' | System | 08 Oct 2020 00:27:09 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Oct 2020 00:27:09 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' User entered '3' | System | 08 Oct 2020 00:27:09 |
|                                                                                                                                                                                                                                                                                 | System | 08 Oct 2020 00:27:09 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:53', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' | System | 08 Oct 2020 00:27:09 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Oct 2020 00:27:09 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

| Audit                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:26:58', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' User entered '1' | System | 08 Oct 2020 00:27:09 |
|                                                                                                                                                                                                                                                                                 | System | 08 Oct 2020 00:27:09 |



US3572167

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:01', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' | System | 08 Oct 2020 00:27:09 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:09 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:04', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'fc389560-dd55-4a67-954b-bd7b8db16944' | System | 08 Oct 2020 00:27:09 |
| User entered '07 Oct 2020 19:27'                                                                                                                                                                                                                               | System | 08 Oct 2020 00:27:09 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:41', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:22:11 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:22:11 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:22:11 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:50', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:22:11 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:53', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:22:11 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:21:57', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Oct 2020 16:22:11 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:22:02', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Oct 2020 16:22:11 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-01T11:22:06', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'cf8a163b-6007-4301-a59e-fdb5ad69c127' | System | 01 Oct 2020 16:22:11 |
| User entered '01 Oct 2020 11:22'                                                                                                                                                                                                                               | System | 01 Oct 2020 16:22:11 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:05' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 13:35' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Oct 2020 15:47:10 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 14:30' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 2' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:15:36', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 20:16:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:15:46', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 02 Oct 2020 20:16:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:15:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 20:16:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:16:11', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'Some interference with activity (2)'                                                                                                                                                                                                             | System | 02 Oct 2020 20:16:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:16:18', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 20:16:47 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:16:30', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Oct 2020 20:16:47 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:16:39', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Oct 2020 20:16:47 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-02T15:16:42', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f3dc587c-3ee2-420b-912c-a9a44b86fcd0' | System | 02 Oct 2020 20:16:47 |
| User entered '02 Oct 2020 15:16'                                                                                                                                                                                                                               | System | 02 Oct 2020 20:16:47 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 3' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:21', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:53 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:28', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:53 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:34', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:53 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:37', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:53 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:53 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:44', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 12:28:53 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:49', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' | System | 04 Oct 2020 12:28:53 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 12:28:53 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T07:28:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'bf70c77e-ab3f-4e7a-a5b4-d10ae67190ff' User entered '04 Oct 2020 07:28' | System | 04 Oct 2020 12:28:53 |
|                                                                                                                                                                                                                                                                                                 | System | 04 Oct 2020 12:28:53 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 4' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:50', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 21:13:25 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:12:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 04 Oct 2020 21:13:25 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:13:05', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 21:13:25 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:13:09', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 21:13:25 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:13:13', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 21:13:25 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:13:16', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Oct 2020 21:13:25 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:13:20', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Oct 2020 21:13:25 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-04T16:13:23', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'beb9317c-903b-4ce9-9898-9bc9d3c4aa46' | System | 04 Oct 2020 21:13:25 |
| User entered '04 Oct 2020 16:13'                                                                                                                                                                                                                               | System | 04 Oct 2020 21:13:25 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 5' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:33', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:58 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:37', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:58 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:39', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:58 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:42', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:58 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:58 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:47', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 01:22:58 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:52', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 01:22:58 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-05T20:22:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'ef445ba7-58ef-4e88-a0fe-1ff8afae272d' | System | 06 Oct 2020 01:22:58 |
| User entered '05 Oct 2020 20:22'                                                                                                                                                                                                                               | System | 06 Oct 2020 01:22:58 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '05 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 6' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:36', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' | System | 06 Oct 2020 23:48:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 23:48:05 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:38', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' | System | 06 Oct 2020 23:48:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 23:48:05 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:40', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' | System | 06 Oct 2020 23:48:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 23:48:05 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                                                  | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:45', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' User entered 'None (0)' | System | 06 Oct 2020 23:48:05 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:48', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' | System | 06 Oct 2020 23:48:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 23:48:05 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:51', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' | System | 06 Oct 2020 23:48:05 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 06 Oct 2020 23:48:05 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' | System | 06 Oct 2020 23:48:05 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 06 Oct 2020 23:48:05 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-06T18:47:59', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '52228a44-4dfd-4f85-aa8c-c5452b32e7d8' User entered '06 Oct 2020 18:47' | System | 06 Oct 2020 23:48:05 |
|                                                                                                                                                                                                                                                                                                 | System | 06 Oct 2020 23:48:05 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '06 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 01 Oct 2020 15:47:10 |
| User entered 'Day 7' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:13', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:57 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:16', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:57 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:21', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:57 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:25', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:57 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:57 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:30', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 00:27:57 |



US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:51', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Oct 2020 00:27:57 |

US3572167

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-07T19:27:54', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'f0a17d3e-77ad-4579-aa00-d1cfcdba923b' | System | 08 Oct 2020 00:27:57 |
| User entered '07 Oct 2020 19:27'                                                                                                                                                                                                                               | System | 08 Oct 2020 00:27:57 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 12:00' | System | 01 Oct 2020 15:47:10 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 11:59' | System | 01 Oct 2020 15:47:10 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 26 Nov 2020 09:37:46

[TIMEPOINT](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Oct 2020 23:47:33 |
| User entered 'Day 8' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 26 Nov 2020 09:37:46

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:10:54', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b4a7850a-11ed-459f-a6da-513d88be20be' | System | 08 Oct 2020 23:11:08 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 08 Oct 2020 23:11:08 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:04', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: 'b4a7850a-11ed-459f-a6da-513d88be20be' User entered '08 Oct 2020 18:11' | System | 08 Oct 2020 23:11:08 |
|                                                                                                                                                                                                                                                                                                 | System | 08 Oct 2020 23:11:08 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 23:47:33 |



US3572167

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Oct 2020 23:47:33 |
| User entered 'Day 8' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Redness\_Day(8)

Generated On: 26 Nov 2020 09:37:46

Is there any REDNESS AT INJECTION SITE?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:17', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9238f9b0-8c7b-45ea-9455-ffe95d8aa859' | System | 08 Oct 2020 23:11:24 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Oct 2020 23:11:24 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:21', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '9238f9b0-8c7b-45ea-9455-ffe95d8aa859' User entered '08 Oct 2020 18:11' | System | 08 Oct 2020 23:11:24 |
|                                                                                                                                                                                                                                                                                                 | System | 08 Oct 2020 23:11:24 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 23:47:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Redness\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Oct 2020 23:47:33 |
| User entered 'Day 8' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:27', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '06fa581a-6281-4833-8e3f-374cdb9182ae' | System | 08 Oct 2020 23:11:34 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 08 Oct 2020 23:11:34 |



US3572167

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 26 Nov 2020 09:37:46

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:31', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '06fa581a-6281-4833-8e3f-374cdb9182ae' User entered '08 Oct 2020 18:11' | System | 08 Oct 2020 23:11:34 |
|                                                                                                                                                                                                                                                                                                 | System | 08 Oct 2020 23:11:34 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 23:47:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 23:47:33 |

US3572167

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 09:37:46

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 06 Oct 2020 23:47:33 |
| User entered 'Day 8' | System | 06 Oct 2020 23:47:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:50', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3d34a1a8-030f-4e7c-ac3e-bf21630d5f10' | System | 08 Oct 2020 23:11:57 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 08 Oct 2020 23:11:57 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-10-08T18:11:55', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '3d34a1a8-030f-4e7c-ac3e-bf21630d5f10' | System | 08 Oct 2020 23:11:57 |
| User entered '08 Oct 2020 18:11'                                                                                                                                                                                                                               | System | 08 Oct 2020 23:11:57 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '08 Oct 2020 12:00' | System | 06 Oct 2020 23:47:33 |

US3572167

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 09:37:46**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '09 Oct 2020 11:59' | System | 06 Oct 2020 23:47:33 |



US3572167

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 08 Oct 2020 20:36:20 |

US3572167

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered '8 Oct 2020' | Jackie Ziegler (b) (4) | 08 Oct 2020 20:36:20 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                         | Time (GMT)           |
|--------------------------------------------|----------------------------------------------|----------------------|
| User signature succeeded.                  | Milton Haber (b) (4)                         | 03 Nov 2020 06:05:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jackie Ziegler (b) (4)<br>(b) (4) | 08 Oct 2020 20:36:20 |

US3572167

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered empty.       | Jackie Ziegler (b) (4) | 08 Oct 2020 20:36:20 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 08 Oct 2020 20:36:28 |

US3572167

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Oct 2020 20:36:28 |

US3572167

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 15 Oct 2020 16:34:11 |

US3572167

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                            | (b) (4)                |                      |
| User entered '15 Oct 2020' | Jackie Ziegler (b) (4) | 15 Oct 2020 16:34:11 |
|                            | (b) (4)                |                      |



US3572167

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                         | Time (GMT)           |
|--------------------------------------------|----------------------------------------------|----------------------|
| User signature succeeded.                  | Milton Haber (b) (4)                         | 03 Nov 2020 06:05:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jackie Ziegler (b) (4)<br>(b) (4) | 15 Oct 2020 16:34:11 |

US3572167

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered empty.       | Jackie Ziegler (b) (4) | 15 Oct 2020 16:34:11 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 15 Oct 2020 16:34:16 |

US3572167

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Oct 2020 16:34:16 |

US3572167

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:07:24 |

US3572167

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:37:46

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                                                                                                                                                         | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).<br>User signature succeeded. | (b) (4), (b) (6)<br>(b) (4)       | 17 Nov 2020 17:16:35 |
|                                                                                                                                                                                                                                                                                                                                                                               | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered '22 Oct 2020'                                                                                                                                                                                                                                                                                                                                                    | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:07:24 |

US3572167

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                         | Time (GMT)           |
|--------------------------------------------|----------------------------------------------|----------------------|
| User signature succeeded.                  | Milton Haber (b) (4)                         | 03 Nov 2020 06:05:19 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:07:24 |

US3572167

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered empty.       | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:07:24 |



US3572167

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:07:30 |

US3572167

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Oct 2020 17:07:30 |

US3572167

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 17:54:35 |

US3572167

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Nov 2020 17:54:35 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Oct 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '03 Nov 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '06 Nov 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '10 Nov 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '13 Nov 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '17 Nov 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-11-21T12:32:49', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '75e1042d-ced4-49e8-b90a-dafa7a9682cf' User entered 'No (N)' | System | 21 Nov 2020 18:33:00 |
|                                                                                                                                                                                                                                                                                      | System | 21 Nov 2020 18:33:00 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-11-21T12:32:53', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '75e1042d-ced4-49e8-b90a-dafa7a9682cf' User entered 'No (N)' | System | 21 Nov 2020 18:33:00 |
|                                                                                                                                                                                                                                                                                      | System | 21 Nov 2020 18:33:00 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32463CEA-28A5-449A-9EB4-4F9E29CE4940)', Time: '2020-11-21T12:32:56', User OID: 'PatientReportedOutcome (US3572167)', ODM File OID: '75e1042d-ced4-49e8-b90a-dafa7a9682cf' User entered '21 Nov 2020 12:32:56' | System | 21 Nov 2020 18:33:00 |
|                                                                                                                                                                                                                                                                                                    | System | 21 Nov 2020 18:33:00 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 02:38:03 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 20 Nov 2020 02:38:03 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 02:38:03 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 20 Nov 2020 02:38:03 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 20 Nov 2020 02:38:03 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 02:38:03 |



US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '04 Nov 2022 00:01' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 09:37:46**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:38:03 |
| Amendment Manager: User entered '08 Nov 2022 23:59' | System | 20 Nov 2020 02:38:03 |

US3572167

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Was Contact Attempted?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:26 |

US3572167

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '23 Nov 2020' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:26 |

US3572167

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:26 |



US3572167

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 09:37:46**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:26 |

US3572167

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Is the participant continuing to the next visit?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:32 |

US3572167

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 09:37:46**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Nov 2020 18:14:32 |

US3572167

**Folder: Covid-19 Assessment 09 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered '9 Sep 2020' | Jackie Ziegler (b) (4) | 09 Sep 2020 14:39:55 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 09 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Time of Contact](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered '09:25'      | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:39:55 |

US3572167

**Folder: Covid-19 Assessment 09 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Date and Time of Contact \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '9 Sep 2020 09:25' | System | 09 Sep 2020 14:39:55 |

US3572167

**Folder: Covid-19 Assessment 09 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Type of Contact](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)                |                      |
| User entered 'Safety Call (Safety Call)' | Jackie Ziegler (b) (4) | 09 Sep 2020 14:39:55 |
|                                          | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 09 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered 'No (N)'     | Jackie Ziegler (b) (4) | 09 Sep 2020 14:39:55 |
|                           | (b) (4)                |                      |



US3572167

**Folder: Covid-19 Assessment 09 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:40:03 |

US3572167

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                            | (b) (4)                |                      |
| User entered '16 Sep 2020' | Jackie Ziegler (b) (4) | 16 Sep 2020 19:01:32 |
|                            | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Time of Contact](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered '13:55'      | Jackie Ziegler (b) (4)<br>(b) (4) | 16 Sep 2020 19:01:32 |

US3572167

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Date and Time of Contact \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '16 Sep 2020 13:55' | System | 16 Sep 2020 19:01:32 |

US3572167

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Type of Contact](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)                |                      |
| User entered 'Safety Call (Safety Call)' | Jackie Ziegler (b) (4) | 16 Sep 2020 19:01:32 |
|                                          | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered 'No (N)'     | Jackie Ziegler (b) (4) | 16 Sep 2020 19:01:32 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 16 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 16 Sep 2020 19:01:56 |

US3572167

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Date of Contact](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                            | (b) (4)                |                      |
| User entered '23 Sep 2020' | Jackie Ziegler (b) (4) | 23 Sep 2020 14:37:24 |
|                            | (b) (4)                |                      |



US3572167

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Time of Contact](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered '09:30'      | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Sep 2020 14:37:24 |

US3572167

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Date and Time of Contact \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 09:30' | System | 23 Sep 2020 14:37:24 |

US3572167

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Type of Contact](#)

| Audit                                    | User                   | Time (GMT)           |
|------------------------------------------|------------------------|----------------------|
| User signature succeeded.                | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                                          | (b) (4)                |                      |
| User entered 'Safety Call (Safety Call)' | Jackie Ziegler (b) (4) | 23 Sep 2020 14:37:24 |
|                                          | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 09:37:46**

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
|                           | (b) (4)                |                      |
| User entered 'No (N)'     | Jackie Ziegler (b) (4) | 23 Sep 2020 14:37:24 |
|                           | (b) (4)                |                      |

US3572167

**Folder: Covid-19 Assessment 23 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 09:37:46**

[Generate Next COVID-19 Assessment](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Sep 2020 14:37:30 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events Summary

**Generated On:** 26 Nov 2020 09:37:46

[Did the participant experience any adverse events?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'    | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:40:09 |

US3572167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:46

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                          | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.' (Site from DM).                                                                                                                                                               | (b) (4), (b) (6)       | 15 Oct 2020 03:13:14 |
| User closed query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).                                                                            | (b) (4), (b) (6)       | 14 Oct 2020 11:16:46 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension aggravated - version MedDRA\23.0.                                                                                                                                                                                                                       | Coder Import (b) (4)   | 09 Oct 2020 00:08:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.                                                                                                                                                                                                                                                                                                                                         | Coder Import (b) (4)   | 09 Oct 2020 00:08:21 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                                                                                                  | System                 | 08 Oct 2020 20:52:41 |
| Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.' answered with 'updated' (Site from DM).                                                                                                                                                   | Jackie Ziegler (b) (4) | 08 Oct 2020 20:52:38 |
| Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Clinic was notified by patient's guardian, medications adjusted per pt' (Site from DM). | Jackie Ziegler (b) (4) | 08 Oct 2020 20:52:26 |
| Coding entries removed.                                                                                                                                                                                                                                                                                                                                                                                                        | Jackie Ziegler (b) (4) | 08 Oct 2020 20:51:46 |
| User entered 'worsening - INCREASED BLOOD PRESSURE' reason for change: Data Entry Error                                                                                                                                                                                                                                                                                                                                        | Jackie Ziegler (b) (4) | 08 Oct 2020 20:51:46 |

US3572167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:46

[Adverse event](#)

| Audit                                                                                                                                                                                                                                                                                                                                               | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). | (b) (4), (b) (6)                  | 06 Oct 2020 11:09:35 |
| User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).                                                                                   | (b) (4), (b) (6)                  | 01 Oct 2020 03:31:32 |
| User coded data point as SOC: Investigations, HLGT: 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)<br>(b) (4)   | 09 Sep 2020 16:06:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                                                         | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 16:06:51 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                       | System                            | 09 Sep 2020 16:05:27 |
| Coding entries removed.                                                                                                                                                                                                                                                                                                                             | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:05:02 |
| User entered 'increased blood pressure' reason for change: Data Entry Error                                                                                                                                                                                                                                                                         | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:05:02 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.                                                                                                                                                                                                     | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 14:43:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.                                                                                                                                                                                                                                                         | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 14:43:43 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                                                       | System                            | 09 Sep 2020 14:42:34 |
| User entered 'headache'                                                                                                                                                                                                                                                                                                                             | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Was this a medically-attended AE?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:46

[Was this a Solicited Adverse Reaction?](#)

| Audit                                                                                                                                                                                                                                                                                             | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).              | (b) (4), (b) (6)       | 15 Oct 2020 03:13:16 |
| Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated ' (Site from DM). | Jackie Ziegler (b) (4) | 08 Oct 2020 20:52:41 |
| User entered 'No (N)' reason for change: Data Entry Error                                                                                                                                                                                                                                         | (b) (4)                | 08 Oct 2020 20:51:46 |
| User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).              | (b) (4), (b) (6)       | 01 Oct 2020 03:31:27 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                            | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Start date \(dd MMM yyyy\)](#)

| Audit                                                         | User                   | Time (GMT)           |
|---------------------------------------------------------------|------------------------|----------------------|
| User entered '7 Sep 2020' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
| User entered '8 Sep 2020'                                     | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Start time \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Ongoing?](#)

| Audit                                                      | User                   | Time (GMT)           |
|------------------------------------------------------------|------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
| User entered 'No (N)'                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
| User entered '9 Sep 2020'                              | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[End time \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Severity](#)

| Audit                                              | User                   | Time (GMT)           |
|----------------------------------------------------|------------------------|----------------------|
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
| reason for change: Data Entry Error                | (b) (4)                |                      |
| User entered 'Grade 1/Mild (Grade 1/Mild)'         | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |
|                                                    | (b) (4)                |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Is the adverse event serious?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Death](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Admitted to ICU?](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Number of Days in ICU](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Relationship to investigational product](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 17 Nov 2020 20:46:11 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 17 Nov 2020 20:46:11 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Maria Candelario (b) (4) | 17 Nov 2020 20:46:11 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 09 Sep 2020 14:42:02 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4)   | 09 Sep 2020 14:42:02 |

US3572167

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                   | 17 Nov 2020 20:46:11 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                   | 17 Nov 2020 20:46:11 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | Maria Candelario (b) (4) | 17 Nov 2020 20:46:11 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                   | 09 Sep 2020 14:42:02 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4)   | 09 Sep 2020 14:42:02 |



US3572167

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Action taken with investigational product](#)

| Audit                                                                                  | User                                | Time (GMT)           |
|----------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                              | 17 Nov 2020 20:46:11 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                              | 17 Nov 2020 20:46:11 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | Maria Candelario (b) (4)<br>(b) (4) | 17 Nov 2020 20:46:11 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                              | 09 Sep 2020 14:42:02 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4)<br>(b) (4)   | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[None](#)

| Audit                                                | User                   | Time (GMT)           |
|------------------------------------------------------|------------------------|----------------------|
| User entered '0' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
|                                                      | (b) (4)                |                      |
| User entered '1'                                     | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |
|                                                      | (b) (4)                |                      |

US3572167

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:37:46

[Concomitant Medication](#)

| Audit                                                                                                                                                                                                                                                                          | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).                | (b) (4), (b) (6)       | 14 Oct 2020 12:27:34 |
| Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'corrected ' (Site from DM). | Jackie Ziegler (b) (4) | 08 Oct 2020 20:53:05 |
| User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).                | (b) (4)                | 01 Oct 2020 03:31:56 |
| User entered '1' reason for change: Data Entry Error                                                                                                                                                                                                                           | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
| User entered '0'                                                                                                                                                                                                                                                               | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Concomitant Procedure](#)

| Audit                                                | User                   | Time (GMT)           |
|------------------------------------------------------|------------------------|----------------------|
| User entered '0' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 08 Oct 2020 20:58:33 |
|                                                      | (b) (4)                |                      |
| User entered '1' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
|                                                      | (b) (4)                |                      |
| User entered '0'                                     | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |
|                                                      | (b) (4)                |                      |

US3572167

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Outcome](#)

| Audit                                                                                          | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 09 Sep 2020 16:05:02 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'                                         | Jackie Ziegler (b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Narrative](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:02 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Sep 2020 14:42:02 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 26 Nov 2020 09:37:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Sep 2020 14:42:02 |

US3572167

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:46

[Adverse event](#)

| Audit                                                                                                                                                                                                        | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash both legs - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)   | 22 Oct 2020 22:15:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                      | Coder Import (b) (4)<br>(b) (4)   | 22 Oct 2020 22:15:22 |
| Data point term sent to Coder                                                                                                                                                                                | System                            | 22 Oct 2020 17:09:59 |
| User entered 'rash on both legs - on calf and shins bilateral'                                                                                                                                               | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Was this a medically-attended AE?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '20 Oct 2020' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Start time \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Oct 2020 17:09:31 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

If not Ongoing, end date (*dd MMM yyyy*)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[End time \(00:00-23:59\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Severity](#)

| Audit                                      | User                              | Time (GMT)           |
|--------------------------------------------|-----------------------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Is the adverse event serious?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Death](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Admitted to ICU?](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Number of Days in ICU](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Relationship to investigational product](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 03 Nov 2020 05:19:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 03 Nov 2020 05:19:48 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | (b) (4), (b) (6)       | 03 Nov 2020 05:19:48 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 22 Oct 2020 17:09:31 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4) | 22 Oct 2020 17:09:31 |
|                                                                                        | (b) (4)                |                      |

US3572167

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:37:46

[Relationship to Study Procedure](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 03 Nov 2020 05:19:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 03 Nov 2020 05:19:48 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | (b) (4), (b) (6)       | 03 Nov 2020 05:19:48 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 22 Oct 2020 17:09:31 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4) | 22 Oct 2020 17:09:31 |
|                                                                                        | (b) (4)                |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Action taken with investigational product](#)

| Audit                                                                                  | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                 | 03 Nov 2020 05:19:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 03 Nov 2020 05:19:48 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | (b) (4), (b) (6)       | 03 Nov 2020 05:19:48 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 22 Oct 2020 17:09:31 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4) | 22 Oct 2020 17:09:31 |
|                                                                                        | (b) (4)                |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[None](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Concomitant Medication](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Concomitant Procedure](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Outcome](#)

| Audit                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |



US3572167

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Narrative](#)

| Audit                                                                                                                           | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'SC50: clinic aware- pt was in clinic for appointment, pictures taken to show MD. no further changes at this time' | Jackie Ziegler (b) (4)<br>(b) (4) | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Oct 2020 17:09:31 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 26 Nov 2020 09:37:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Oct 2020 17:09:31 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[AEID](#)

| Audit                                                 | User             | Time (GMT)           |
|-------------------------------------------------------|------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6) | 18 Nov 2020 13:13:57 |
| Reviewed for Safety.                                  | (b) (4), (b) (6) | 02 Nov 2020 20:33:00 |
| User entered<br>'USA-US091-2020-mRNA-1273-P301000002' | System           | 02 Nov 2020 20:32:40 |
| User entered 'New'                                    | (b) (4), (b) (6) | 02 Nov 2020 20:32:40 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Adverse event](#)

| Audit                                                                                                                                                                                                                    | User                                | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                      | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:55 |
| User closed query 'PV Urgent Query: Please provide the event term.' (Site from Safety).                                                                                                                                  | (b) (4), (b) (6)                    | 11 Nov 2020 14:05:57 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Accelerated and malignant hypertension, PT: Accelerated hypertension, LLT: Accelerated hypertension - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)     | 10 Nov 2020 21:39:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.                                                                                                                                  | Coder Import (b) (4)<br>(b) (4)     | 10 Nov 2020 21:39:41 |
| Query 'PV Urgent Query: Please provide the event term.' answered with 'updated' (Site from Safety).                                                                                                                      | Maria Candelario (b) (4)<br>(b) (4) | 10 Nov 2020 14:52:29 |
| Data point term sent to Coder                                                                                                                                                                                            | System                              | 10 Nov 2020 14:47:22 |
| User entered 'Acelerated Hypertension' reason for change: Data Entry Error                                                                                                                                               | Maria Candelario (b) (4)<br>(b) (4) | 10 Nov 2020 14:46:24 |
| User opened query 'PV Urgent Query: Please provide the event term.' (Site from Safety).                                                                                                                                  | (b) (4), (b) (6)                    | 05 Nov 2020 17:27:40 |
| Data point term sent to Coder                                                                                                                                                                                            | System                              | 30 Oct 2020 20:07:34 |
| User entered 'Initial SAE report'                                                                                                                                                                                        | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Was this a medically-attended AE?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 18 Nov 2020 13:13:54 |
| User entered 'No (N)' | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                       | (b) (4)                  |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:52 |
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:49 |
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 18 Nov 2020 13:13:48 |
| User entered '27 Oct 2020' | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                            | (b) (4)                  |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Start time \(00:00-23:59\)](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 13:13:46 |
| User entered empty. | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                     | (b) (4)                  |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Ongoing?](#)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)         | 18 Nov 2020 13:13:45 |
| User entered 'No (N)' reason for change: Data Entry Error | Maria Candelario (b) (4) | 10 Nov 2020 14:11:11 |
| User entered 'Yes (Y)'                                    | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

If not Ongoing, end date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                   | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                     | (b) (4), (b) (6)         | 18 Nov 2020 13:13:43 |
| 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)         | 11 Nov 2020 14:06:03 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).                                                         | (b) (4), (b) (6)         | 11 Nov 2020 04:43:12 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).                                             | Maria Candelario (b) (4) | 10 Nov 2020 14:53:06 |
| 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' (Site from Safety). | Maria Candelario (b) (4) | 10 Nov 2020 14:52:35 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).                                                         | System                   | 10 Nov 2020 14:11:11 |
| User entered '30 Oct 2020' reason for change: Data Entry Error                                                                                                                                                          | Maria Candelario (b) (4) | 10 Nov 2020 14:11:11 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).             | (b) (4), (b) (6)         | 09 Nov 2020 23:15:30 |
| User entered empty.                                                                                                                                                                                                     | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

End time (00:00-23:59)

| Audit                                                                                                                                                                               | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                 | (b) (4), (b) (6)         | 20 Nov 2020 17:15:38 |
| User closed query 'Per source, end time is not noted nor is required for event longer than 24 hours. Please review and delete if not applicable.' (Site from CRA).                  | (b) (4), (b) (6)         | 20 Nov 2020 17:15:36 |
| Query 'Per source, end time is not noted nor is required for event longer than 24 hours. Please review and delete if not applicable.' answered with 'Data updated' (Site from CRA). | Maria Candelario (b) (4) | 18 Nov 2020 19:56:29 |
| DataPoint Un-verified.                                                                                                                                                              | (b) (4)                  |                      |
|                                                                                                                                                                                     | Maria Candelario (b) (4) | 18 Nov 2020 19:55:20 |
| User entered empty; reason for change Data Entry Error                                                                                                                              | Maria Candelario (b) (4) | 18 Nov 2020 19:55:20 |
| DataPoint Verified.                                                                                                                                                                 | (b) (4), (b) (6)         | 18 Nov 2020 13:13:40 |
| User opened query 'Per source, end time is not noted nor is required for event longer than 24 hours. Please review and delete if not applicable.' (Site from CRA).                  | (b) (4), (b) (6)         | 18 Nov 2020 13:12:14 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).                                  | (b) (4), (b) (6)         | 11 Nov 2020 04:43:19 |
| Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'updated' (Site from System).                      | Maria Candelario (b) (4) | 10 Nov 2020 14:53:08 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).                                  | System                   | 10 Nov 2020 14:11:11 |
| User entered '12:11' reason for change: Data Entry Error                                                                                                                            | Maria Candelario (b) (4) | 10 Nov 2020 14:11:11 |
| User entered empty.                                                                                                                                                                 | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[AE End Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 18 Nov 2020 19:55:20 |
| User entered '30 Oct 2020 12:11' | System | 10 Nov 2020 14:11:11 |
| User entered empty.              | System | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Severity](#)

| Audit                                                                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                       | (b) (4), (b) (6)         | 18 Nov 2020 13:13:38 |
| User closed query 'Data is required. Please complete.' (Site from System).                                | (b) (4), (b) (6)         | 05 Nov 2020 04:07:42 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error                        | (b) (4), (b) (6)         | 03 Nov 2020 05:18:16 |
| Query 'Data is required. Please complete.' answered with 'pending additional records' (Site from System). | Maria Candelario (b) (4) | 30 Oct 2020 20:10:58 |
| User opened query 'Data is required. Please complete.' (Site from System).                                | (b) (4)                  |                      |
| User entered empty.                                                                                       | System                   | 30 Oct 2020 20:07:11 |
|                                                                                                           | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                                                                                                           | (b) (4)                  |                      |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Is the adverse event serious?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:36 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Death](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:33 |
| User entered '0'    | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 13:13:31 |
| User entered '0'    | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                     | (b) (4)                  |                      |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                                                                                                                                                                                                                                                                    | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                                      | (b) (4), (b) (6)         | 18 Nov 2020 13:13:30 |
| User closed query 'Per CDM: Please provide the additional records details.' (Site from DM).                                                                                                                                                                              | (b) (4), (b) (6)         | 11 Nov 2020 04:43:36 |
| Query 'Per CDM: Please provide the additional records details.' answered with 'updated' (Site from DM).                                                                                                                                                                  | Maria Candelario (b) (4) | 10 Nov 2020 14:53:19 |
| User opened query 'Per CDM: Please provide the additional records details.' (Site from DM).                                                                                                                                                                              | (b) (4), (b) (6)         | 09 Nov 2020 06:29:34 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                | (b) (4), (b) (6)         | 09 Nov 2020 06:27:21 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Pending additional records' (Site from System). | Maria Candelario (b) (4) | 30 Oct 2020 20:09:22 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                | System                   | 30 Oct 2020 20:07:11 |
| User entered '1'                                                                                                                                                                                                                                                         | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:28 |
| User entered '27 Oct 2020' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

Hospital Discharge Date (dd MMM yyyy)

| Audit                                                                                                                    | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                      | (b) (4), (b) (6)         | 18 Nov 2020 13:13:24 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).             | (b) (4), (b) (6)         | 11 Nov 2020 14:06:10 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety). | Maria Candelario (b) (4) | 10 Nov 2020 14:53:35 |
| User entered '30 Oct 2020' reason for change: Data Entry Error                                                           | (b) (4)                  | 10 Nov 2020 14:46:24 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).             | (b) (4), (b) (6)         | 09 Nov 2020 23:15:18 |
| User entered empty.                                                                                                      | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Admitted to ICU?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:21 |
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Number of Days in ICU](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 13:13:18 |
| User entered empty. | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                     | (b) (4)                  |                      |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:16 |
| User entered '0'    | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:15 |
| User entered '0'    | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)         | 18 Nov 2020 13:13:13 |
| User entered '0'    | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                     | (b) (4)                  |                      |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Relationship to investigational product](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:12 |
| User entered 'Not Related (NOT RELATED)' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

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**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Relationship to Study Procedure](#)

| Audit                                    | User                                | Time (GMT)           |
|------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:10 |
| User entered 'Not Related (NOT RELATED)' | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Action taken with investigational product](#)

| Audit                                          | User                     | Time (GMT)           |
|------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 18 Nov 2020 13:13:09 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |
|                                                | (b) (4)                  |                      |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[None](#)

| Audit                                                                                                                              | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                                                                                                | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:03 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System                              | 03 Nov 2020 05:18:16 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System                              | 30 Oct 2020 20:07:11 |
| User entered '0'                                                                                                                   | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Concomitant Medication](#)

| Audit                                                | User                                | Time (GMT)           |
|------------------------------------------------------|-------------------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:02 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6)                    | 03 Nov 2020 05:18:16 |
| User entered '0'                                     | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |



US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Concomitant Procedure](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 13:13:00 |
| User entered '0'    | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Outcome](#)

| Audit                                                                                                                                                                                                                                                | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                                                                                                  | (b) (4), (b) (6)         | 18 Nov 2020 13:12:59 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).             | (b) (4), (b) (6)         | 11 Nov 2020 14:06:17 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). | Maria Candelario (b) (4) | 10 Nov 2020 14:55:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:                                                                                                                                                                            | Maria Candelario (b) (4) | 10 Nov 2020 14:54:39 |
| Data Entry Error                                                                                                                                                                                                                                     |                          |                      |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).             | (b) (4), (b) (6)         | 09 Nov 2020 23:15:48 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                           | (b) (4), (b) (6)         | 05 Nov 2020 04:11:33 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:                                                                                                                                                                        | (b) (4), (b) (6)         | 03 Nov 2020 05:18:16 |
| Data Entry Error                                                                                                                                                                                                                                     |                          |                      |
| Query 'Data is required. Please complete.' answered with 'pending records' (Site from System).                                                                                                                                                       | Maria Candelario (b) (4) | 30 Oct 2020 20:08:35 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                           | System                   | 30 Oct 2020 20:07:11 |
| User entered empty.                                                                                                                                                                                                                                  | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

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**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 18 Nov 2020 13:12:57 |
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 30 Oct 2020 20:07:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                           | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User opened query 'PV Query: Please provide BP measurements from baseline and relevant BP measurements documenting the event accelerated hypertension. ' (Site from Safety).                                                                                                                                                                                                    | (b) (4), (b) (6)                    | 20 Nov 2020 14:31:21 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).             | (b) (4), (b) (6)                    | 20 Nov 2020 14:31:08 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).                                                                                                                                                                                                   | (b) (4), (b) (6)                    | 20 Nov 2020 14:30:54 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                                                             | (b) (4), (b) (6)                    | 18 Nov 2020 13:12:55 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).             | (b) (4), (b) (6)                    | 11 Nov 2020 14:06:28 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                                  | (b) (4), (b) (6)                    | 11 Nov 2020 14:06:23 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending' (Site from Safety). | Maria Candelario (b) (4)<br>(b) (4) | 10 Nov 2020 14:55:28 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).                                                                                                                                                                                      | Maria Candelario (b) (4)<br>(b) (4) | 10 Nov 2020 14:55:11 |

US3572167

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 09:37:46

[Narrative](#)

| Audit                                                                                                                                                                                                                                                                                                                                                               | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User entered 'Subject had an admission on 10/27/2020. Long history of Hypertension/morbid obesity with sleep apnea' reason for change: Data Entry Error                                                                                                                                                                                                             | Maria Candelario (b) (4) | 10 Nov 2020 14:46:24 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6)         | 09 Nov 2020 23:15:57 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).                                                                                                                                                                                      | (b) (4), (b) (6)         | 09 Nov 2020 23:15:40 |
| User entered 'Pending Records'                                                                                                                                                                                                                                                                                                                                      | Maria Candelario (b) (4) | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 30 Oct 2020 20:07:11 |

US3572167

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 26 Nov 2020 09:37:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 30 Oct 2020 20:07:11 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 09:37:46**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                                                                                                                                                                                                                                                                                     | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| Query 'Per review of SAE records, was metoprolol, lovenox or potassium chloride ever started? If yes, please add to EDC.' answered with 'Confirmed metoprolol, Lovenox and potassium chloride was started post discharge from hospital. Con meds will be added to EDC. ' (Site from CRA). | Alisha Lutat (b) (4)<br>(b) (4)   | 19 Nov 2020 23:01:15 |
| User opened query 'Per review of SAE records, was metoprolol, lovenox or potassium chloride ever started? If yes, please add to EDC.' (Site from CRA).                                                                                                                                    | (b) (4), (b) (6)<br>(b) (4)       | 12 Nov 2020 21:40:35 |
| DataPoint Verified.                                                                                                                                                                                                                                                                       | (b) (4), (b) (6)<br>(b) (4)       | 12 Nov 2020 21:39:35 |
| User signature succeeded.                                                                                                                                                                                                                                                                 | Milton Haber (b) (4)<br>(b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                    | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:42:56 |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:37:46

Name of Medication

| Audit                                                                                                                                                                                                                                                                             | User                              | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                        | (b) (4), (b) (6)                  | 10 Sep 2020 07:28:38 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL, PRODUCTSYNONYM: TENORMIN - version WHODrug-Global-B3\\202003.                                                 | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 16:14:44 |
| 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)   | 09 Sep 2020 16:14:44 |
| Data point term sent to Coder                                                                                                                                                                                                                                                     | System                            | 09 Sep 2020 16:13:40 |
| User entered 'tenormin' reason for change: Data Entry Error                                                                                                                                                                                                                       | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:12:59 |
| Data point term sent to Coder                                                                                                                                                                                                                                                     | System                            | 09 Sep 2020 15:00:21 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System).                                                                                                                                                                                              | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 15:00:06 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                        | System                            | 09 Sep 2020 14:59:50 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                            | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:59:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 14:44:47 |
| 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)   | 09 Sep 2020 14:44:47 |
| Data point term sent to Coder                                                                                                                                                                                                                                                     | System                            | 09 Sep 2020 14:43:40 |
| User entered 'Imodium'                                                                                                                                                                                                                                                            | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:28:40 |
| User entered 'No (N)' reason for change: Data Entry Error                            | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:16 |
| User entered empty; reason for change Data Entry Error                               | (b) (4)                |                      |
| User entered 'No (N)'                                                                | System                 | 09 Sep 2020 14:59:50 |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
|                                                                                      | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:28:45 |
| User entered 'htn' reason for change: Data Entry Error                               | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:23 |
| User opened query 'Data is required. Please complete.' (Site from System).           | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | System                 | 09 Sep 2020 14:59:50 |
| User entered empty; reason for change Data Entry Error                               | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
| User entered 'loose stools'                                                          | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:28:47 |
| User entered '100' reason for change: Data Entry Error                               | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:29 |
| User opened query 'Data is required. Please complete.' (Site from System).           | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | System                 | 09 Sep 2020 14:59:50 |
| User entered empty; reason for change Data Entry Error                               | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
| User entered '2'                                                                     | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:28:51 |
| User entered 'mg (mg)' reason for change: Data Entry Error                           | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:34 |
|                                                                                      | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | System                 | 09 Sep 2020 14:59:50 |
| User entered empty; reason for change Data Entry Error                               | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
|                                                                                      | (b) (4)                |                      |
| User entered 'mg (mg)'                                                               | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 11 Sep 2020 07:58:36 |
| User entered 'twice daily (BID)' reason for change: Data Entry Error                 | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:38 |
|                                                                                      | (b) (4)                |                      |
| User entered empty; reason for change Data Entry Error                               | System                 | 09 Sep 2020 14:59:50 |
| User entered 'as needed (PRN)'                                                       | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
|                                                                                      | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:28:55 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error                       | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:43 |
| User entered empty; reason for change Data Entry Error                               | (b) (4)                |                      |
| User entered 'Oral (ORAL)'                                                           | System                 | 09 Sep 2020 14:59:50 |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
|                                                                                      | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                                                           | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System                 | 09 Sep 2020 16:12:59 |
| User entered '8 Sep 2020' reason for change: Data Entry Error                                                                   | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System                 | 09 Sep 2020 14:59:50 |
| User entered empty; reason for change Data Entry Error                                                                          | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
| User entered '2 Sep 2020'                                                                                                       | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:29:00 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                           | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:47 |
| User entered empty; reason for change Data Entry Error                               | (b) (4)                |                      |
| User entered 'Yes (Y)'                                                               | System                 | 09 Sep 2020 14:59:50 |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
|                                                                                      | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                                                                                | User                   | Time (GMT)           |
|--------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).           | (b) (4), (b) (6)       | 10 Sep 2020 07:29:02 |
| User entered 'No (N)' reason for change: Data Entry Error                            | Jackie Ziegler (b) (4) | 09 Sep 2020 16:12:59 |
| Query 'Data is required. Please complete.' answered with 'error' (Site from System). | (b) (4)                |                      |
| User opened query 'Data is required. Please complete.' (Site from System).           | Jackie Ziegler (b) (4) | 09 Sep 2020 15:00:51 |
| User entered empty; reason for change Data Entry Error                               | (b) (4)                |                      |
| User entered 'Yes (Y)'                                                               | System                 | 09 Sep 2020 14:59:50 |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:59:50 |
|                                                                                      | (b) (4)                |                      |
|                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:39 |
|                                                                                      | (b) (4)                |                      |



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2'    | System | 09 Sep 2020 16:12:59 |
| User entered empty. | System | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 09 Sep 2020 16:12:59 |
| User entered empty. | System | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Sep 2020 16:12:59 |
| User entered empty.      | System | 09 Sep 2020 14:43:39 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                            | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>ANTIHYPERTENSIVES, ATC: ARTERIOLAR<br>SMOOTH MUSCLE, AGENTS ACTING ON, ATC:<br>HYDRAZINOPHTHALAZINE DERIVATIVES,<br>PRODUCT: HYDRALAZINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 16:16:29 |
| 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)   | 09 Sep 2020 16:16:29 |
| Data point term sent to Coder                                                                                                                                                                                                                    | System                            | 09 Sep 2020 16:14:42 |
| User entered 'hydralazine'                                                                                                                                                                                                                       | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered 'HTN' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit                                                 | User                   | Time (GMT)           |
|-------------------------------------------------------|------------------------|----------------------|
| User entered '100' reason for change: New Information | Jackie Ziegler (b) (4) | 23 Sep 2020 14:37:53 |
| User entered '75'                                     | Jackie Ziegler (b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                                  | User                              | Time (GMT)           |
|----------------------------------------|-----------------------------------|----------------------|
| User entered 'three times daily (TID)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                         | User                   | Time (GMT)           |
|---------------------------------------------------------------|------------------------|----------------------|
| User entered '22 Sep 2020' reason for change: New Information | Jackie Ziegler (b) (4) | 23 Sep 2020 14:37:53 |
| User entered '8 Sep 2020'                                     | Jackie Ziegler (b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                                                    | User                   | Time (GMT)           |
|----------------------------------------------------------|------------------------|----------------------|
| User entered 'No (N)' reason for change: New Information | Jackie Ziegler (b) (4) | 23 Nov 2020 18:13:40 |
| User entered 'Yes (Y)'                                   | Jackie Ziegler (b) (4) | 09 Sep 2020 16:13:55 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                                                          | User                   | Time (GMT)           |
|----------------------------------------------------------------|------------------------|----------------------|
| User entered '30 Oct 2020' reason for change: Data Entry Error | Jackie Ziegler (b) (4) | 23 Nov 2020 18:13:40 |
| User entered empty.                                            | Jackie Ziegler (b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Sep 2020 16:13:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                                                  | User                              | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| 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: NAPROXEN<br>SODIUM, PRODUCTSYNONYM: ALEVE -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 09 Sep 2020 16:15:43 |
| 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)   | 09 Sep 2020 16:15:43 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                                          | System                            | 09 Sep 2020 16:14:44 |
| User entered 'aleve'                                                                                                                                                                                                                                                                                                   | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                                                                                                                                                                                                                                                                                                                     | User                              | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please update the indication to reflect the location and type of pain. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).                                                                                                              | (b) (4), (b) (6)                  | 23 Nov 2020 06:54:09 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of pain. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' answered with 'Confirmed Pain was related to a headache, which has since been removed as the AE was an anticipated AR. ' (Site from DM). | Alisha Lutat (b) (4)<br>(b) (4)   | 19 Nov 2020 23:08:00 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of pain. Review and update indication and ensure to update Adverse event eCRF as appropriate. ' (Site from DM).                                                                                                              | (b) (4), (b) (6)                  | 27 Oct 2020 09:17:02 |
| User entered 'pain'                                                                                                                                                                                                                                                                                                       | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '220' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'as needed (PRN)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| User entered '8 Sep 2020' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | User                   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Pain is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Pain did not meet the AE reporting criteria.' (Site from DM).                                                                                                     | (b) (4), (b) (6)       | 23 Nov 2020 06:55:47 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Pain is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Pain did not meet the AE reporting criteria.' answered with 'Confirmed conmed was taken for headache, which has been removed due to being an anticipated AR ' (Site from DM). | Alisha Lutat (b) (4)   | 19 Nov 2020 23:08:50 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the Pain is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of Pain did not meet the AE reporting criteria.' (Site from DM).                                                                                                     | (b) (4), (b) (6)       | 09 Oct 2020 03:25:05 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Jackie Ziegler (b) (4) | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 16:14:25 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                   | User                   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 09 Sep 2020 16:16:45 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                               | Coder Import (b) (4)   | 09 Sep 2020 16:16:45 |
| Data point term sent to Coder                                                                                                                                                                                                                                           | System                 | 09 Sep 2020 16:15:47 |
| User entered 'vitamin d'                                                                                                                                                                                                                                                | Jackie Ziegler (b) (4) | 09 Sep 2020 16:15:17 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                               | User                              | Time (GMT)           |
|-------------------------------------|-----------------------------------|----------------------|
| User entered 'vitamin d deficiency' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '10000' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'IU (IU)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[If dose unit is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                                                                                  | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | System                            | 09 Sep 2020 16:15:50 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                            | 09 Sep 2020 16:15:50 |
| User entered 'other (OTHER)' reason for change: Data Entry Error                       | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:50 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                            | 09 Sep 2020 16:15:17 |
| User entered empty.                                                                    | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit                                                                                                          | User                              | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System). | System                            | 09 Sep 2020 16:16:06 |
| User entered 'pt did not state' reason for change: Data Entry Error                                            | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:16:06 |
| User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System). | System                            | 09 Sep 2020 16:15:50 |
| User entered empty.                                                                                            | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Aug 1990' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 16:15:17 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Sep 2020 16:15:17 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                   | User                   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 09 Sep 2020 16:18:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                                                                                               | Coder Import (b) (4)   | 09 Sep 2020 16:18:48 |
| Data point term sent to Coder                                                                                                                                                                                                                                           | System                 | 09 Sep 2020 16:17:54 |
| User entered 'levothyroxin'                                                                                                                                                                                                                                             | Jackie Ziegler (b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                         | User                              | Time (GMT)           |
|-------------------------------|-----------------------------------|----------------------|
| User entered 'hypothyroidism' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '75' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                                                                                                                                                                                                                                                                                                             | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.<br>' (Site from DM).                                                | (b) (4), (b) (6)                  | 23 Nov 2020 06:56:40 |
| User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).                                                                                                                                                                                               | System                            | 19 Nov 2020 23:05:08 |
| Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.<br>' answered with 'data entry error; Dose unit changed to 'ug" (Site from DM). | Alisha Lutat (b) (4)<br>(b) (4)   | 19 Nov 2020 23:05:04 |
| User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).                                                                                                                                                                                               | System                            | 19 Nov 2020 23:04:19 |
| User entered 'ug (ug)' reason for change: Data Entry Error                                                                                                                                                                                                                                                        | Alisha Lutat (b) (4)<br>(b) (4)   | 19 Nov 2020 23:04:19 |
| User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.<br>' (Site from DM).                                                | (b) (4), (b) (6)                  | 09 Oct 2020 03:26:16 |
| User entered 'Other (OTHER)'                                                                                                                                                                                                                                                                                      | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[If dose unit is Other, specify](#)

| Audit                                                  | User                   | Time (GMT)           |
|--------------------------------------------------------|------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Alisha Lutat (b) (4)   | 19 Nov 2020 23:05:08 |
| User entered 'mcg'                                     | Jackie Ziegler (b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '01 Aug 1990' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:03 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Sep 2020 16:17:03 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                  | User                              | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE, PRODUCTSYNONYM: RISPERDAL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 14 Sep 2020 11:45:41 |
| 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 Sep 2020 11:45:41 |
| Data point term sent to Coder                                                                                                                                                                          | System                            | 09 Sep 2020 16:18:56 |
| User entered 'respiradal'                                                                                                                                                                              | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'autism' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '0.5' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                                  | User                              | Time (GMT)           |
|----------------------------------------|-----------------------------------|----------------------|
| User entered 'three times daily (TID)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '02 Oct 2005' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Sep 2020 16:17:55 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Sep 2020 16:17:55 |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:37:46

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                            | User                                          | Time (GMT)                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------------------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC:<br>ACE INHIBITORS, PLAIN, PRODUCT:<br>LISINOPRIL - version<br>WHODrug-Global-B3\\202003.      | Coder Import (b) (4)<br>(b) (4)               | 19 Nov 2020 23:51:50                         |
| 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)               | 19 Nov 2020 23:51:50                         |
| Data point term sent to Coder<br>Coding entries removed.                                                                                                                                                                                         | System<br>Maria Candelario (b) (4)<br>(b) (4) | 19 Nov 2020 23:50:43<br>19 Nov 2020 23:49:59 |
| User entered 'Lisinopril' reason for change: Data<br>Entry Error                                                                                                                                                                                 | Maria Candelario (b) (4)<br>(b) (4)           | 19 Nov 2020 23:49:59                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>ANTIHYPERTENSIVES, ATC: ARTERIOLAR<br>SMOOTH MUSCLE, AGENTS ACTING ON, ATC:<br>HYDRAZINOPHTHALAZINE DERIVATIVES,<br>PRODUCT: HYDRALAZINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 05 Oct 2020 18:15:30                         |
| 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)               | 05 Oct 2020 18:15:30                         |
| Data point term sent to Coder<br>User entered 'hydralazine'                                                                                                                                                                                      | System<br>(b) (4), (b) (6)                    | 05 Oct 2020 18:14:33<br>05 Oct 2020 18:13:51 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                       |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                       | User             | Time (GMT)           |
|-----------------------------|------------------|----------------------|
| User entered 'hypertension' | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                             |                  |                      |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit                                                | User                        | Time (GMT)           |
|------------------------------------------------------|-----------------------------|----------------------|
| User entered '5' reason for change: Data Entry Error | Maria Candelario (b) (4)    | 19 Nov 2020 23:49:59 |
| User entered '100'                                   | (b) (4)<br>(b) (4), (b) (6) | 05 Oct 2020 18:13:51 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                        |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[If dose unit is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                     |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                                               | User                     | Time (GMT)           |
|-----------------------------------------------------|--------------------------|----------------------|
| User entered 'twice daily (BID)' reason for change: | Maria Candelario (b) (4) | 19 Nov 2020 23:49:59 |
| Data Entry Error                                    | (b) (4)                  |                      |
| User entered 'three times daily (TID)'              | (b) (4), (b) (6)         | 05 Oct 2020 18:13:51 |
|                                                     |                          |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                     |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                            |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                     |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                                                                                   | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                   | 23 Nov 2020 18:13:04 |
| User entered '00 2020' (non-conformant).                                                | Jackie Ziegler (b) (4)   | 23 Nov 2020 18:13:04 |
|                                                                                         | (b) (4)                  |                      |
| User entered '07 Nov 2020' reason for change: Data Entry Error                          | Maria Candelario (b) (4) | 19 Nov 2020 23:49:59 |
|                                                                                         | (b) (4)                  |                      |
| User entered '22 Sep 2020'                                                              | (b) (4), (b) (6)         | 05 Oct 2020 18:13:51 |
|                                                                                         |                          |                      |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                  |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                                                    | User                              | Time (GMT)           |
|----------------------------------------------------------|-----------------------------------|----------------------|
| User entered 'No (N)' reason for change: New Information | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:11:30 |
| User entered 'Yes (Y)'                                   | (b) (4), (b) (6)                  | 05 Oct 2020 18:13:51 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                                                                                    | User                   | Time (GMT)           |
|------------------------------------------------------------------------------------------|------------------------|----------------------|
| User closed query 'End date is prior to start date. Please correct.' (Site from System). | System                 | 23 Nov 2020 18:13:04 |
| User opened query 'End date is prior to start date. Please correct.' (Site from System). | System                 | 23 Nov 2020 18:11:30 |
| User entered '30 Oct 2020' reason for change: Data Entry Error                           | Jackie Ziegler (b) (4) | 23 Nov 2020 18:11:30 |
| User entered empty.                                                                      | (b) (4)                |                      |
|                                                                                          | (b) (4), (b) (6)       | 05 Oct 2020 18:13:51 |
|                                                                                          |                        |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 05 Oct 2020 18:13:51 |
|                       |                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 19 Nov 2020 23:49:59 |
| User entered '3' | System | 05 Oct 2020 18:13:51 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:13:51 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 18:13:51 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                      | User                            | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC:<br>DIURETICS, ATC: HIGH-CEILING DIURETICS,<br>ATC: SULFONAMIDES, PLAIN, PRODUCT:<br>FUROSEMIDE, PRODUCTSYNONYM: LASIX<br>[FUROSEMIDE] - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 18 Nov 2020 07:27:02 |
| 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 Nov 2020 07:27:02 |
| Data point term sent to Coder                                                                                                                                                                                                              | System                          | 18 Nov 2020 01:01:19 |
| User entered 'Furosemide (Lasix)'                                                                                                                                                                                                          | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                                        | User                            | Time (GMT)           |
|----------------------------------------------|---------------------------------|----------------------|
| User entered 'Mild Congestive Heart Failure' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit             | User                            | Time (GMT)           |
|-------------------|---------------------------------|----------------------|
| User entered '20' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'mg (mg)' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[If dose unit is Other, specify](#)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User entered 'once daily (QD)' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User entered '07 Nov 2020' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                            | Time (GMT)           |
|------------------|---------------------------------|----------------------|
| User entered '0' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                            | Time (GMT)           |
|------------------------|---------------------------------|----------------------|
| User entered 'Yes (Y)' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                            | Time (GMT)           |
|---------------------|---------------------------------|----------------------|
| User entered empty. | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                            | Time (GMT)           |
|-----------------------|---------------------------------|----------------------|
| User entered 'No (N)' | Alisha Lutat (b) (4)<br>(b) (4) | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Nov 2020 01:00:27 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 01:00:27 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                 | User                                | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: BETA<br>BLOCKING AGENTS, ATC: BETA BLOCKING<br>AGENTS, ATC: BETA BLOCKING AGENTS,<br>SELECTIVE, PRODUCT: METOPROLOL<br>SUCCINATE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 20 Nov 2020 03:39:54 |
| 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)     | 20 Nov 2020 03:39:54 |
| Data point term sent to Coder                                                                                                                                                                                                         | System                              | 20 Nov 2020 00:02:57 |
| User entered 'Metoprolol Succ ER'                                                                                                                                                                                                     | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                       | User                                | Time (GMT)           |
|-----------------------------|-------------------------------------|----------------------|
| User entered 'Hypertension' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit             | User                                | Time (GMT)           |
|-------------------|-------------------------------------|----------------------|
| User entered '25' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| User entered 'mg (mg)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[If dose unit is Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| User entered 'once daily (QD)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User entered '7 Nov 2020' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                                | Time (GMT)           |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:02:43 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Nov 2020 00:02:43 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Nov 2020 00:02:43 |

US3572167

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:37:46

[Name of Medication](#)

| Audit                                                                                                                                                                                     | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 20 Nov 2020 00:21:56 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                 | Coder Import (b) (4)     | 20 Nov 2020 00:21:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 20 Nov 2020 00:06:50 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                 | Coder Import (b) (4)     | 20 Nov 2020 00:06:50 |
| Data point term sent to Coder                                                                                                                                                             | System                   | 20 Nov 2020 00:05:58 |
| User entered 'Potassium Chloride'                                                                                                                                                         | Maria Candelario (b) (4) | 20 Nov 2020 00:05:10 |
|                                                                                                                                                                                           | (b) (4)                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                       | User                                | Time (GMT)           |
|-----------------------------|-------------------------------------|----------------------|
| User entered 'Hypertension' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit             | User                                | Time (GMT)           |
|-------------------|-------------------------------------|----------------------|
| User entered '10' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                        | User                                | Time (GMT)           |
|------------------------------|-------------------------------------|----------------------|
| User entered 'Other (OTHER)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[If dose unit is Other, specify](#)

| Audit              | User                                | Time (GMT)           |
|--------------------|-------------------------------------|----------------------|
| User entered 'mEq' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                          | User                                | Time (GMT)           |
|--------------------------------|-------------------------------------|----------------------|
| User entered 'once daily (QD)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| User entered '7 Nov 2020' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                                | Time (GMT)           |
|------------------|-------------------------------------|----------------------|
| User entered '0' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Nov 2020 00:05:10 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                      | User                                | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN HEMIHYDRATE, PRODUCTSYNONYM: LEVONOX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)     | 21 Nov 2020 09:04:47 |
| 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)     | 21 Nov 2020 09:04:47 |
| Data point term sent to Coder                                                                                                                                                                                                                              | System                              | 20 Nov 2020 19:53:50 |
| User entered 'Levonox'                                                                                                                                                                                                                                     | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit              | User                                | Time (GMT)           |
|--------------------|-------------------------------------|----------------------|
| User entered 'DVT' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit              | User                                | Time (GMT)           |
|--------------------|-------------------------------------|----------------------|
| User entered 'unk' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                                                                                          | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                     | (b) (4), (b) (6)         | 23 Nov 2020 07:09:52 |
| Query 'Data is required. Please complete.' answered with 'Dose is unknown' (Site from System). | Maria Candelario (b) (4) | 20 Nov 2020 19:54:04 |
| User opened query 'Data is required. Please complete.' (Site from System).                     | (b) (4)                  | 20 Nov 2020 19:53:49 |
| User entered empty.                                                                            | System                   | 20 Nov 2020 19:53:49 |
|                                                                                                | Maria Candelario (b) (4) | 20 Nov 2020 19:53:49 |
|                                                                                                | (b) (4)                  |                      |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

If dose unit is Other, specify

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User entered 'once (ONCE)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4), (b) (6)         | 23 Nov 2020 07:09:54 |
| Query 'Data is required. Please complete.' answered with 'Unknown' (Site from System). | Maria Candelario (b) (4) | 20 Nov 2020 19:54:15 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                  | 20 Nov 2020 19:53:49 |
| User entered empty.                                                                    | Maria Candelario (b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                                | Time (GMT)           |
|------------------|-------------------------------------|----------------------|
| User entered '1' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User entered '30 Oct 2020' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                                | Time (GMT)           |
|-----------------------|-------------------------------------|----------------------|
| User entered 'No (N)' | Maria Candelario (b) (4)<br>(b) (4) | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 19:53:49 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Name of Medication](#)

| Audit                                                                                                                                                                                                                                                                                           | User                              | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), PLAIN, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS), PLAIN, PRODUCT: VALSARTAN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 23 Nov 2020 19:53:09 |
| 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 19:53:09 |
| Data point term sent to Coder                                                                                                                                                                                                                                                                   | System                            | 23 Nov 2020 18:14:21 |
| User entered 'Valsartan'                                                                                                                                                                                                                                                                        | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Prophylaxis](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                       | User                              | Time (GMT)           |
|-----------------------------|-----------------------------------|----------------------|
| User entered 'hypertension' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose per administration](#)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '160' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Dose unit](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

If dose unit is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Frequency](#)

| Audit                          | User                              | Time (GMT)           |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[If frequency is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

If route of administration is Other, specify

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '30 Oct 2020' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Start date completely unknown](#)

| Audit            | User                              | Time (GMT)           |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Ongoing?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Was this medication taken for solicited event?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Jackie Ziegler (b) (4)<br>(b) (4) | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Nov 2020 18:14:19 |



US3572167

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 26 Nov 2020 09:37:46**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 23 Nov 2020 18:14:19 |

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 09:37:46**

[Were any concomitant procedures performed?](#)

| Audit                                                                                                                                                                                                                | User                   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User opened query 'Per CDM: On "Were any concomitant procedures performed?" page is was mentioned as YES. however, on Concomitant Procedures form no data was captured. Kindly, update accordingly.' (Site from DM). | (b) (4), (b) (6)       | 20 Nov 2020 05:20:25 |
| User signature succeeded.                                                                                                                                                                                            | Milton Haber (b) (4)   | 03 Nov 2020 06:05:19 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                                                                                                                                                           | (b) (4)                |                      |
|                                                                                                                                                                                                                      | Jackie Ziegler (b) (4) | 09 Sep 2020 16:18:04 |
|                                                                                                                                                                                                                      | (b) (4)                |                      |
| User entered 'No (N)'                                                                                                                                                                                                | Jackie Ziegler (b) (4) | 09 Sep 2020 14:43:46 |
|                                                                                                                                                                                                                      | (b) (4)                |                      |

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

| Audit                                                                                                                                 | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                                            | (b) (4), (b) (6)         | 20 Nov 2020 05:18:46 |
| Query 'Data is required. Please complete.' answered with 'Data deleted as subject didn't have con-med procedures' (Site from System). | Maria Candelario (b) (4) | 18 Nov 2020 23:09:37 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                            | (b) (4)                  |                      |
| User entered empty; reason for change Data Entry Error                                                                                | System                   | 18 Nov 2020 23:08:48 |
| User entered '8 Sep 2020'                                                                                                             | Maria Candelario (b) (4) | 18 Nov 2020 23:08:48 |
|                                                                                                                                       | (b) (4)                  |                      |
|                                                                                                                                       | Jackie Ziegler (b) (4)   | 09 Sep 2020 16:18:38 |
|                                                                                                                                       | (b) (4)                  |                      |

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Procedure/Surgery](#)

| Audit                                                                                                                                                                                                                                                                         | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please confirm recorded data and delete if appropriate, otherwise clarify.' (Site from DM).                                                            | (b) (4), (b) (6)         | 20 Nov 2020 05:19:13 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                    | (b) (4), (b) (6)         | 20 Nov 2020 05:19:11 |
| Query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please confirm recorded data and delete if appropriate, otherwise clarify.' answered with 'Data deleted as subject didn't have con-med procedures' (Site from DM). | Maria Candelario (b) (4) | 18 Nov 2020 23:09:42 |
| Query 'Data is required. Please complete.' answered with 'Data deleted as subject didn't have con-med procedures' (Site from System).                                                                                                                                         | (b) (4)                  | 18 Nov 2020 23:09:35 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                    | System                   | 18 Nov 2020 23:08:48 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                        | Maria Candelario (b) (4) | 18 Nov 2020 23:08:48 |
| User opened query 'Per DM CLR: Please note that only procedures or non-drug therapies are to be recorded in this page. Please confirm recorded data and delete if appropriate, otherwise clarify.' (Site from DM).                                                            | (b) (4), (b) (6)         | 24 Sep 2020 15:30:33 |
| User entered 'pt was seen at urgent care for increased blood pressure'                                                                                                                                                                                                        | Jackie Ziegler (b) (4)   | 09 Sep 2020 16:18:38 |

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:37:46**

[Indication](#)

| Audit                                                                                                                                 | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                                                            | (b) (4), (b) (6)         | 20 Nov 2020 05:19:19 |
| Query 'Data is required. Please complete.' answered with 'Data deleted as subject didn't have con-med procedures' (Site from System). | Maria Candelario (b) (4) | 18 Nov 2020 23:09:33 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                            | (b) (4)                  |                      |
| User entered empty.                                                                                                                   | System                   | 09 Sep 2020 16:18:38 |
|                                                                                                                                       | Jackie Ziegler (b) (4)   | 09 Sep 2020 16:18:38 |
|                                                                                                                                       | (b) (4)                  |                      |

US3572167

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 09:37:46**

[If indication is Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Jackie Ziegler (b) (4)<br>(b) (4) | 09 Sep 2020 16:18:38 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded.                             | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered<br>'USA-US091-2020-MRNA-1273-P301000002' | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Milton'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Haber'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Street](#)

| Audit                                         | User                        | Time (GMT)           |
|-----------------------------------------------|-----------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 11 Nov 2020 14:06:40 |
| Un-reviewed for Safety.                       | System                      | 04 Nov 2020 13:10:38 |
| Signature has been broken.                    | System                      | 04 Nov 2020 13:10:38 |
| User entered '2344 Laguna Del Mar, Suite 201' | System                      | 04 Nov 2020 13:10:38 |
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded.                     | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '2344 Laguna Del Mar, Suite 104' | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Laredo'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'TX'         | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '78041'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)     | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered 'US'         | (b) (4)<br>System    | 02 Nov 2020 20:33:50 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User entered '4'           | System               | 19 Nov 2020 22:46:26 |
| User entered '3'           | System               | 11 Nov 2020 14:06:53 |
| Signature has been broken. | System               | 04 Nov 2020 13:10:38 |
| User entered '2'           | System               | 04 Nov 2020 13:10:38 |
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '1'           | System               | 02 Nov 2020 20:33:50 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded.                             | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered<br>'USA-US091-2020-MRNA-1273-P301000002' | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Milton'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Haber'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Street](#)

| Audit                                         | User                        | Time (GMT)           |
|-----------------------------------------------|-----------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 11 Nov 2020 14:06:40 |
| Un-reviewed for Safety.                       | System                      | 04 Nov 2020 13:10:38 |
| Signature has been broken.                    | System                      | 04 Nov 2020 13:10:38 |
| User entered '2344 Laguna Del Mar, Suite 201' | System                      | 04 Nov 2020 13:10:38 |
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded.                     | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '2344 Laguna Del Mar, Suite 104' | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Laredo'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'TX'         | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '78041'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)     | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered 'US'         | (b) (4)<br>System    | 02 Nov 2020 20:33:50 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User entered '4'           | System               | 19 Nov 2020 22:46:26 |
| User entered '3'           | System               | 11 Nov 2020 14:06:53 |
| Signature has been broken. | System               | 04 Nov 2020 13:10:38 |
| User entered '2'           | System               | 04 Nov 2020 13:10:38 |
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '1'           | System               | 02 Nov 2020 20:33:50 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form (1)

**Generated On:** 26 Nov 2020 09:37:46

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered '02/Nov/2020 20:33' | (b) (4)<br>System    | 02 Nov 2020 20:33:50 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)     | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered '1'          | (b) (4), (b) (6)     | 02 Nov 2020 20:33:50 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded.                             | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered<br>'USA-US091-2020-MRNA-1273-P301000002' | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Milton'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Haber'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Street](#)

| Audit                                         | User                        | Time (GMT)           |
|-----------------------------------------------|-----------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 11 Nov 2020 14:06:40 |
| Un-reviewed for Safety.                       | System                      | 04 Nov 2020 13:10:38 |
| Signature has been broken.                    | System                      | 04 Nov 2020 13:10:38 |
| User entered '2344 Laguna Del Mar, Suite 201' | System                      | 04 Nov 2020 13:10:38 |
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded.                     | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '2344 Laguna Del Mar, Suite 104' | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Laredo'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'TX'         | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '78041'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)     | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered 'US'         | (b) (4)<br>System    | 02 Nov 2020 20:33:50 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User entered '4'           | System               | 19 Nov 2020 22:46:26 |
| User entered '3'           | System               | 11 Nov 2020 14:06:53 |
| Signature has been broken. | System               | 04 Nov 2020 13:10:38 |
| User entered '2'           | System               | 04 Nov 2020 13:10:38 |
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '1'           | System               | 02 Nov 2020 20:33:50 |



US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form (2)

**Generated On:** 26 Nov 2020 09:37:46

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04/Nov/2020 13:10' | System | 04 Nov 2020 13:10:38 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Nov 2020 14:06:40 |
| User entered '1'     | (b) (4), (b) (6) | 04 Nov 2020 13:10:38 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded.                             | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered<br>'USA-US091-2020-MRNA-1273-P301000002' | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Milton'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Haber'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Street](#)

| Audit                                         | User                        | Time (GMT)           |
|-----------------------------------------------|-----------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 11 Nov 2020 14:06:40 |
| Un-reviewed for Safety.                       | System                      | 04 Nov 2020 13:10:38 |
| Signature has been broken.                    | System                      | 04 Nov 2020 13:10:38 |
| User entered '2344 Laguna Del Mar, Suite 201' | System                      | 04 Nov 2020 13:10:38 |
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded.                     | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '2344 Laguna Del Mar, Suite 104' | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Laredo'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'TX'         | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '78041'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)     | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered 'US'         | (b) (4)<br>System    | 02 Nov 2020 20:33:50 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User entered '4'           | System               | 19 Nov 2020 22:46:26 |
| User entered '3'           | System               | 11 Nov 2020 14:06:53 |
| Signature has been broken. | System               | 04 Nov 2020 13:10:38 |
| User entered '2'           | System               | 04 Nov 2020 13:10:38 |
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '1'           | System               | 02 Nov 2020 20:33:50 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form (3)

**Generated On:** 26 Nov 2020 09:37:46

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '11/Nov/2020 14:06' | System | 11 Nov 2020 14:06:53 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 22:46:10 |
| User entered '1'     | (b) (4), (b) (6) | 11 Nov 2020 14:06:53 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[SAEID](#)

| Audit                                                 | User                        | Time (GMT)           |
|-------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded.                             | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered<br>'USA-US091-2020-MRNA-1273-P301000002' | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |



US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'Yes (Y)'    | System                      | 02 Nov 2020 20:32:40 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form

**Generated On:** 26 Nov 2020 09:37:46

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Nov 2020 20:33:39 |
| User entered 'No (N)'     | System                      | 02 Nov 2020 20:32:40 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Milton'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Haber'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Street](#)

| Audit                                         | User                        | Time (GMT)           |
|-----------------------------------------------|-----------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 11 Nov 2020 14:06:40 |
| Un-reviewed for Safety.                       | System                      | 04 Nov 2020 13:10:38 |
| Signature has been broken.                    | System                      | 04 Nov 2020 13:10:38 |
| User entered '2344 Laguna Del Mar, Suite 201' | System                      | 04 Nov 2020 13:10:38 |
| Reviewed for Safety.                          | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded.                     | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '2344 Laguna Del Mar, Suite 104' | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'Laredo'     | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |



US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered 'TX'         | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

Site Address: [Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4)        | 03 Nov 2020 06:05:19 |
| User entered '78041'      | (b) (4)<br>(b) (4), (b) (6) | 03 Nov 2020 05:16:39 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)     | 04 Nov 2020 13:10:26 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
| User entered 'US'         | (b) (4)<br>System    | 02 Nov 2020 20:33:50 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:37:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User entered '4'           | System               | 19 Nov 2020 22:46:26 |
| User entered '3'           | System               | 11 Nov 2020 14:06:53 |
| Signature has been broken. | System               | 04 Nov 2020 13:10:38 |
| User entered '2'           | System               | 04 Nov 2020 13:10:38 |
| User signature succeeded.  | Milton Haber (b) (4) | 03 Nov 2020 06:05:19 |
|                            | (b) (4)              |                      |
| User entered '1'           | System               | 02 Nov 2020 20:33:50 |

US3572167

**Folder:** SAE USA-US091-2020-MRNA-1273-P301000002

**Form:** Safety Report Form (4)

**Generated On:** 26 Nov 2020 09:37:46

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '19/Nov/2020 22:46' | System | 19 Nov 2020 22:46:26 |

US3572167

Folder: SAE USA-US091-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:37:46

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '1' | (b) (4), (b) (6) | 19 Nov 2020 22:46:26 |