

US3342286 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:57:53

All time stamps listed in this document are displayed in GMT

US3342286

Form: Participant Creation

Generated On: 26 Nov 2020 10:57:53

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[Participant ID](#)

US3342286

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

Generated On: 26 Nov 2020 10:57:53

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1983   |
| Age                                       | 37   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 37   |
| 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

Generated On: 26 Nov 2020 10:57:53

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 26 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

Generated On: 26 Nov 2020 10:57:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:53

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

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



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

|   |  |
|---|--|
| Condition   | RIGHT NECK STABBING (~ 4 IN DEEP)                                |
| Start date (dd MMM yyyy)                          | UN UNK 2010  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2010  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2010   |
| Start Year (derived)                              | 2010   |
| Stop Month and Year (derived)                     | JAN 2010   |
| Stop Year (derived)                               | 2010   |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 26 SEP 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:18 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 26 SEP 2020 11:18                    |
| Height ( <i>xxx.x</i> )                   | 170.5 cm                             |
| Weight ( <i>xxx.x</i> )                   | 84.6 kg                              |
| BMI ( <i>xxx.x</i> )                      | 29.10192 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

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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

Generated On: 26 Nov 2020 10:57:53

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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**

---

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

**No Risk Identified** False

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

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

|  |       |
|--|-------|
| <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

Generated On: 26 Nov 2020 10:57:53

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 26 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 10:57:53

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

What was the participant's randomization number? 115486

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 10:57:53

|        |               |
|--------|---------------|
| 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 10:57:53

|                                     |  |
|-------------------------------------|--|
| 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)    | 26 SEP 2020  |
| Time of assessment (00:00-23:59)    | 11:31 (24 HR)  |
| Vital Signs Date and Time (derived) | 26 SEP 2020 11:31  |
| Temperature (xxx.x)                 | 98.0 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 86 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 14 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 149 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 93 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 10:57:53

|                                     |  |
|-------------------------------------|--|
| 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)    | 26 SEP 2020  |
| Time of assessment (00:00-23:59)    | 12:51 (24 HR)  |
| Vital Signs Date and Time (derived) | 26 SEP 2020 12:51  |
| Temperature (xxx.x)                 | 98.6 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 80 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 12 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 146 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 94 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

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

Generated On: 26 Nov 2020 10:57:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:18 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 12:18

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

Generated On: 26 Nov 2020 10:57:53

|  |                                      |
|--|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 26 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 12:09 (24 HR)                        |
| Collection date and time (derived)     | 26 SEP 2020 12:09                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:53

| Collection date (dd MMM yyyy) |                           |                                 | 26 SEP 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 12:10                           | 26 SEP 2020 12:10                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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 10:57:53

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

26 SEP 2020 12:52

PC Open Date & Time

26 SEP 2020 12:38

PC Close Date & Time

26 SEP 2020 15:08

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.5 °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        | 27 SEP 2020 09:09 |
| PC Open Date & Time  | 26 SEP 2020 16:03 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.7 °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

27 SEP 2020 15:21

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

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US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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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 ☒

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

Yes ☐

No ☒

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

---

PC Time Stamp 28 SEP 2020 16:31

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

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US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

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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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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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

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

30 SEP 2020 22:00

---

PC Open Date & Time

30 SEP 2020 12:00

---

PC Close Date & Time

01 OCT 2020 11:59

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US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

---

**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 ☒

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 09:41

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

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US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**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 ☒

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 23:59

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**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

26 SEP 2020 12:53

PC Open Date & Time

26 SEP 2020 12:38

PC Close Date & Time

26 SEP 2020 15:08

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**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

27 SEP 2020 09:10

PC Open Date & Time

26 SEP 2020 16:03

PC Close Date & Time

27 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 15:21

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**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

28 SEP 2020 16:31

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**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

29 SEP 2020 12:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**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

30 SEP 2020 22:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 09:41

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 00:00

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**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 ☐

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 26 SEP 2020 12:53 |
| PC Open Date & Time  | 26 SEP 2020 12:38 |
| PC Close Date & Time | 26 SEP 2020 15:08 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**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 ☐

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 27 SEP 2020 09:10 |
| PC Open Date & Time  | 26 SEP 2020 16:03 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**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 ☒

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 SEP 2020 15:22 |
| PC Open Date & Time          | 27 SEP 2020 12:00 |
| PC Close Date & Time         | 28 SEP 2020 11:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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 ☒



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 SEP 2020 16:32 |
| PC Open Date & Time          | 28 SEP 2020 12:00 |
| PC Close Date & Time         | 29 SEP 2020 11:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**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 ☒

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 SEP 2020 12:01 |
| PC Open Date & Time          | 29 SEP 2020 12:00 |
| PC Close Date & Time         | 30 SEP 2020 11:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**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 ☒

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 SEP 2020 22:01 |
| PC Open Date & Time          | 30 SEP 2020 12:00 |
| PC Close Date & Time         | 01 OCT 2020 11:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**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 ☒

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 OCT 2020 09:41 |
| PC Open Date & Time          | 01 OCT 2020 12:00 |
| PC Close Date & Time         | 02 OCT 2020 11:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**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 ☒



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 00:01 |
| PC Open Date & Time          | 02 OCT 2020 12:00 |
| PC Close Date & Time         | 03 OCT 2020 11:59 |

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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



US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 26 OCT 2020                               |
| Time of assessment (00:00-23:59)    | 13:50 (24 HR)                             |
| Vital Signs Date and Time (derived) | 26 OCT 2020 13:50                         |
| Temperature (xxx.x)                 | 98.3 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 83 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 12 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 181 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 127 mmHg                                  |
| Diastolic Blood Pressure units      | MMHG                                      |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

US3342286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

|  |                                      |
|--|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 26 OCT 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 14:31 (24 HR)                        |
| Collection date and time (derived)     | 26 OCT 2020 14:31                    |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:53

| Collection date (dd MMM yyyy) |                           |                                 | 26 OCT 2020                        |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 14:33                           | 26 OCT 2020 14:33                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 20 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 20 NOV 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 08:46 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 20 NOV 2020 08:46                     |
| Temperature ( <i>xxx.x</i> )              | 98.6 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 80 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 14 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 174 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 109 mmHg                              |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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



US3342286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

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

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

US3342286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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27 NOV 2020 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 DEC 2020 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 07 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 11 DEC 2020 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | 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 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 DEC 2020 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 28 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 01 JAN 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 103   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JAN 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 JAN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JAN 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 JAN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 JAN 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JAN 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 01 FEB 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 FEB 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 138   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 15 FEB 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 FEB 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 152

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

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 FEB 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 FEB 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 01 MAR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 MAR 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 MAR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 MAR 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 29 MAR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 02 APR 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 208

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

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 APR 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 APR 2021 23:59 |



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Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 MAY 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 MAY 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 JUN 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 JUN 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 278  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 28 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 02 JUL 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 05 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 JUL 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 19 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 23 JUL 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 306   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 02 AUG 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 06 AUG 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 09 AUG 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 AUG 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 AUG 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 341  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 SEP 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 13 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 SEP 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 20 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 SEP 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 369   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 04 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 08 OCT 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 OCT 2021 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 OCT 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 25 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 OCT 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 NOV 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 NOV 2021 23:59 |
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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 432  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 29 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 03 DEC 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 446   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 13 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 DEC 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 20 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 DEC 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 27 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 31 DEC 2021 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 JAN 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 24 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 JAN 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 31 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 04 FEB 2022 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 FEB 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 516   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 FEB 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 APR 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 579   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 MAY 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 MAY 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 635   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 642

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 656  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JUL 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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 ☐

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 JUL 2022 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 25 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUL 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 684   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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| Date and time of submission |  |
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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 08 AUG 2022 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 12 AUG 2022 23:59 |
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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 AUG 2022 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 AUG 2022 23:59 |
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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 AUG 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 SEP 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 12 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 SEP 2022 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 733  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 26 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 SEP 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 03 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 07 OCT 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 OCT 2022 23:59 |



US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| TIMEPOINT   | DAY 754  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

| 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"/>   |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3342286**

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

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**Generated On: 26 Nov 2020 10:57:53**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2022 23:59

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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

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

[Patient Cloud Close Date & Time](#)

18 NOV 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 NOV 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 NOV 2022 23:59 |

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 28 NOV 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 02 DEC 2022 23:59 |

US3342286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

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*

US3342286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3342286

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:53

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

**US3342286**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 26 Nov 2020 10:57:53**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 10:57:53**

|  |             |
|--|-------------|
| Visit Date   | 21 OCT 2020 |
| Please check all assessments that apply for this visit |             |
| Physical Exam  | True        |
| Vital Signs  | True        |
| Immunogenicity Assessment                              | False       |
| Pregnancy Test   | False       |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 21 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:27 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 21 OCT 2020 13:27                     |
| Temperature ( <i>xxx.x</i> )              | 98.3 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 63 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 14 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 165 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 109 mmHg                              |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3342286

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | HYPERTENSION (UNSPECIFIED)   |
| 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)                                       | 21 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 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  |  |
| Persistent or significant disability or incapacity             | False  |
| v6.020 DTW (1102)  |  |
| 302 of 1249  |  |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

|  |   |
|--|---|
| 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 checked="" type="radio"/><br>Investigational Product 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  |   |



US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

---

CALLED PT TO F/U ON  
ELEVATED BP. PT DID NOT  
ANSWER, BUT PI LEFT  
DETAILED VOICEMAIL.  
REMINDED PT OF VISIT AND  
RECOMMENDATION HE SEE A  
PCP RE: BP. THIS  
RECOMMENDATION WAS  
REITERATED BY DR. PICKRELL  
AT A SUBSEQUENT VISIT. PI  
OFFERED THAT WE HAVE A  
LIST OF ACCESSIBLE CLINICS  
IN CASE PT IN UNABLE TO SEE  
HIS WIFE'S MD AS HE HOPED. PI  
SPECIFICALLY MENTIONED  
LONE STAR CIRCLE OF CARE,  
WHICH HAS LOCATIONS IN  
TRAVIS AND WILLIAMSON  
COUNTIES. LIST OBTAINED  
FROM CITY OF AUSTIN  
WEBSITE, WHICH PI  
REFERENCED TO HIM. (b) (6)  
(b) (6) 02NOV2020.

UPDATE: AT PT VISIT 3  
(20NOV20230) PT WAS ASKED IF  
HE F/U WITH PCP/MEDICAL  
PROVIDER REGARDING  
ELEVATED BP. PT STATED  
THAT HE HAD NOT FOLLOWED  
UP WITH ANYONE IRT THE  
ELEVATED BP. PT STILL  
INTENDS ON SEEING MEDICAL  
PROVIDER (SPECIFICALLY  
STATING "LONE STAR") AFTER  
THANKSGIVING. HE WAS  
INFORMED THAT HE WOULD

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

---

BE ABLE TO HAVE AN  
APPOINTMENT AT THAT TIME.  
PT NEEDS TO CALL CLINIC IN  
ORDER TO SCHEDULED  
APPOINTMENT AFTER  
THANKSGIVING. WILL F/U  
WITH PT AND MONITOR FOR  
ADDITIONAL INFORMATION.  
DUE TO PATIENT'S ELEVATED  
BP AT VISIT 3, SX DIRECTED  
PHYSICAL CONDUCTED  
FOCUSED ON  
CARDIOVASCULAR  
ASSESSMENT. DAO 20NOV2020.

---

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

---

US3342286

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

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

**Generated On: 26 Nov 2020 10:57:53**

---

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

Yes ☒

No ☐

---

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

---

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:53

|                                |  |
|--------------------------------|--|
| Name of Medication             | DIPHENHYDRAMINE  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | SEASONAL ALLERGIES   |
| Dose per administration        | 50   |
| 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"/>  |

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:53

|   |                          |                                  |
|---|--------------------------|----------------------------------|
|   | 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)  | UN                       | UNK 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)                                  | <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"/>            |

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:53

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | IBUPROFEN  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | GENERALIZED PAIN   |
| Dose per administration              | 200  |
| 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"/>  |

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:53

|   |                                      |                                     |
|---|--------------------------------------|-------------------------------------|
|   | 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)  | UN UNK 2000                          |                                     |
| 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"/>               |

US3342286

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:57:53**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

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

---



US3342286

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:53

Date of dosing discontinuation (dd MMM yyyy)

21 OCT 2020

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

AE: HYPERTENSION,  
UNSPECIFIED.

US3342286

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:57:53

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3342286 (Prod: Tekton Research- Austin)

**US3342286**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:57:53**

[Participant ID](#)

| Audit                    | User  | Time (GMT)           |
|--------------------------|---|----------------------|
| User entered 'US3342286' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Sep 2020 16:26:03 |

US3342286

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

[Was this visit performed?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:13 |

US3342286

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| User entered '26 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Sep 2020 16:26:05 |

US3342286

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:13 |

**US3342286**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:53**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 26 Sep 2020 16:59:13 |



US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| User entered (b) (6) 1983' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 26 Sep 2020 16:26:06 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Age](#)

| Audit             | User                               | Time (GMT)           |
|-------------------|------------------------------------|----------------------|
| User entered '37' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '37' | System | 26 Sep 2020 16:59:39 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Sex](#)

| Audit                   | User                               | Time (GMT)           |
|-------------------------|------------------------------------|----------------------|
| User entered 'Male (M)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Ethnicity](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

White

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Black](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |



US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Asian](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[American Indian or Alaska Native](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Other](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

If race is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

Unknown

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:53

[Not reported](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:24 |

US3342286

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:53

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '26 Sep 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:39 |



US3342286

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:53**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Sep 2020' | System | 26 Sep 2020 16:59:39 |

US3342286

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:53**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 26 Sep 2020 16:59:39 |

US3342286

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:53

[Protocol Version](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| User entered 'Amendment 3 (3)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:39 |

US3342286

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:39 |

US3342286

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:53

If No, indicate reason for screen fail

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:39 |

US3342286

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:53**

If reason for screen fail is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:39 |

US3342286

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:53**

[Was this participant screened previously?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:39 |

US3342286

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:53

[If Yes, previous participant number](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 26 Sep 2020 16:26:05 |



US3342286

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:53**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Sep 2020 16:59:44 |

US3342286

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 16:59:44 |

US3342286

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:53

[Were any significant conditions reported?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:17 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

[Condition](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)    | 26 Sep 2020 17:03:44 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)    | 26 Sep 2020 17:03:44 |
| Data point term sent to Coder  | System                             | 26 Sep 2020 17:03:00 |
| User entered 'Seasonal Allergies'  | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un Jan 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

[Condition ongoing at study entry](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System                  | 26 Sep 2020 17:02:54 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | Darrell O'Brien (b) (4) | 26 Sep 2020 17:02:54 |
| User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | System                  | 26 Sep 2020 17:02:42 |
| User entered 'No (N)'  | Darrell O'Brien (b) (4) | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:42 |



US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2020' | System | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

Start Year (derived)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:02:42 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

[Condition](#)

| Audit  | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Stab wound, LLT: Stab wound - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)    | 27 Sep 2020 04:36:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)    | 27 Sep 2020 04:36:37 |
| Data point term sent to Coder  | System                             | 26 Sep 2020 17:04:02 |
| User entered 'Right Neck Stabbing (~ 4 in deep)'   | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2010' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:40 |



US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

[Condition ongoing at study entry](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:40 |

US3342286

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:57:53**

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2010' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 26 Sep 2020 17:03:40 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

[Condition](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0. | Coder Import (b) (4)    | 26 Sep 2020 17:04:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)    | 26 Sep 2020 17:04:45 |
| Data point term sent to Coder  | System                  | 26 Sep 2020 17:04:02 |
| User entered 'Generalized Pain'  | Darrell O'Brien (b) (4) | 26 Sep 2020 17:03:09 |
|  | (b) (4)                 |                      |



US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2000' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

[Condition ongoing at study entry](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2000' | System | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:03:09 |



US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:03:09 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

[Condition](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\23.0. | Coder Import (b) (4)    | 14 Oct 2020 08:46:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)    | 14 Oct 2020 08:46:29 |
| Data point term sent to Coder  | System                  | 26 Sep 2020 17:05:03 |
| User entered 'Surgery for Right Neck Stabbing'   | Darrell O'Brien (b) (4) | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2010' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

[Condition ongoing at study entry](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2010' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

[Stop date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 26 Sep 2020 17:04:12 |



US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2010' | System | 26 Sep 2020 17:04:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Were vital signs assessed?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '26 Sep 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                | User                               | Time (GMT)           |
|----------------------|------------------------------------|----------------------|
| User entered '11:18' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:18' | System | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '170.5' cm   | Darrell O'Brien (b) (4) | 26 Sep 2020 17:02:12 |
| DataPoint set to visible. | (b) (4)<br>System       | 26 Sep 2020 16:59:44 |



US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered '84.6' kg    | Darrell O'Brien (b) (4) | 26 Sep 2020 17:02:12 |
| DataPoint set to visible. | (b) (4)<br>System       | 26 Sep 2020 16:59:44 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

BMI (xxx.x)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered '29.10192'   | System | 26 Sep 2020 17:02:12 |
| DataPoint set to visible. | System | 26 Sep 2020 16:59:44 |

**US3342286**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:53**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 26 Sep 2020 17:02:12 |
| DataPoint set to visible. | System | 26 Sep 2020 16:59:44 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

**US3342286**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:53**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Sep 2020 17:02:12 |



US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Diastolic Blood Pressure (xxx)

| Audit                                    | User                               | Time (GMT)           |
|--|------------------------------------|----------------------|
| User entered missing code ND - Not Done. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Sep 2020 17:02:12 |

US3342286

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:05 |

US3342286

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Date of examination (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '26 Sep 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:05 |



US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**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 entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |



US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

[Other](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

[Specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

No Risk Identified

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |



US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

[Other](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:53

[Specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:01:29 |

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

[Was this visit performed?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:06:05 |

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '26 Sep 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:06:05 |

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:06:05 |



**US3342286**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:53**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 26 Sep 2020 17:06:05 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| User entered '26 SEP 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Sep 2020 16:57:38 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

What was the participant's randomization number?

| Audit                 | User  | Time (GMT)           |
|-----------------------|---|----------------------|
| User entered '115486' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Sep 2020 16:57:38 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

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

| Audit   | User   | Time (GMT)           |
|---|--|----------------------|
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 26 Sep 2020 16:57:38 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

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

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:00:53 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

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

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:00:53 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

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

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:00:53 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:00:53 |



US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

[Liver Disease](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:00:53 |

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:53

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| User entered 'No (N)'     | Darrell O'Brien (b) (4) | 26 Sep 2020 17:00:53 |
| DataPoint set to visible. | (b) (4)<br>System       | 26 Sep 2020 16:59:39 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:53

Height

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:53

Weight

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:53

Height

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:53

Weight

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Timepoint](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Were vital signs assessed?

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |



US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '26 Sep 2020' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '11:31' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:31' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '98.0' F | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '86' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Sep 2020 18:05:17 |



US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '14' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '149' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Diastolic Blood Pressure (xxx)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '93' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:53

[Height](#)

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:53

Weight

| Audit                                    | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered missing code ND - Not Done. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |



US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Timepoint](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Were vital signs assessed?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '26 Sep 2020' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '12:51' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:51' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered '98.6' F | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (Oral)' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |



US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '80' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '12' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit              | User                              | Time (GMT)           |
|--------------------|-----------------------------------|----------------------|
| User entered '146' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Diastolic Blood Pressure (xxx)

| Audit             | User                              | Time (GMT)           |
|-------------------|-----------------------------------|----------------------|
| User entered '94' | Eileen Euperio (b) (4)<br>(b) (4) | 26 Sep 2020 18:05:17 |

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Sep 2020 18:05:17 |



US3342286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:06:13 |

US3342286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Date of examination (*dd MMM yyyy*)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:06:13 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

[Was study treatment given?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

If No, reason not given

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '26 Sep 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit                | User                               | Time (GMT)           |
|----------------------|------------------------------------|----------------------|
| User entered '12:18' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:24:07 |



US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:18' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

Which arm was used to give treatment?

| Audit                              | User                               | Time (GMT)           |
|------------------------------------|------------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

What was the route of administration for the study treatment?

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:00 |

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

Collection date (dd MMM yyyy)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Query 'Per IMMUNO Lab Recon: GCL has an<br>Unscheduled lab with date of 26SEP2020; however it<br>is recorded in EDC for Visit 1 Day 1. Please confirm<br>collection date of 26SEP2020 is for Visit 1 Day 1 or<br>else clarify.<br>' answered with 'COLLECTION DATE OF<br>26SEP2020 IS FOR VISIT 1' (Site from DM). | Morgan Schulle (b) (4)<br>(b) (4) | 05 Oct 2020 16:07:24 |
| User opened query 'Per IMMUNO Lab Recon: GCL<br>has an Unscheduled lab with date of 26SEP2020;<br>however it is recorded in EDC for Visit 1 Day 1.<br>Please confirm collection date of 26SEP2020 is for<br>Visit 1 Day 1 or else clarify.<br>' (Site from DM).  | (b) (4), (b) (6)<br>(b) (4)       | 04 Oct 2020 08:43:32 |
| User entered '26 Sep 2020'   | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:00 |

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

Collection time (00:00-23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '12:09' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:00 |

**US3342286**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:57:53**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:09' | System | 28 Sep 2020 18:53:00 |



US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:53

Collection date (dd MMM yyyy)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).  | (b) (4), (b) (6)          | 24 Nov 2020 10:12:27 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'The sample reported at 26SEP2020 was collected for Visit 1 Day 1. It is reported as "unscheduled" because an unscheduled lab kit was used due to lab kit shortage.' (Site from DM). | Olivia Hapanowicz (b) (4) | 17 Nov 2020 17:30:08 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).  | (b) (4), (b) (6)          | 23 Oct 2020 08:13:36 |
| User entered '26 Sep 2020'   | Morgan Schulle (b) (4)    | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

[Lab Test](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

Collection time (00:00 - 23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '12:10' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:10' | System | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

[Lab Test](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Morgan Schulle (b) (4) | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

[Was the sample collected?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

Collection time (00:00 - 23:59)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Morgan Schulle (b) (4)<br>(b) (4) | 28 Sep 2020 18:53:13 |



**US3342286**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:57:53**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Sep 2020 18:53:13 |

US3342286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:25:04 |

US3342286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Sep 2020 17:25:04 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' | System | 26 Sep 2020 17:52:47 |
| User entered 'Yes (Y)'   | System | 26 Sep 2020 17:52:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:27', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' | System | 26 Sep 2020 17:52:47 |
| User entered '98.6'  | System | 26 Sep 2020 17:52:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' | System | 26 Sep 2020 17:52:47 |
| User entered 'No (N)'  | System | 26 Sep 2020 17:52:47 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' | System | 26 Sep 2020 17:52:47 |
| User entered '26 Sep 2020 12:52'   | System | 26 Sep 2020 17:52:47 |



US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:38' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 15:08' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:20', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' | System | 27 Sep 2020 14:09:41 |
| User entered 'Yes (Y)'   | System | 27 Sep 2020 14:09:41 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' | System | 27 Sep 2020 14:09:41 |
| User entered '98.5'  | System | 27 Sep 2020 14:09:41 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' | System | 27 Sep 2020 14:09:41 |
| User entered 'No (N)'  | System | 27 Sep 2020 14:09:41 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:39', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' | System | 27 Sep 2020 14:09:41 |
| User entered '27 Sep 2020 09:09'   | System | 27 Sep 2020 14:09:41 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 16:03' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 2' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:20:56', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' | System | 27 Sep 2020 20:21:10 |
| User entered 'Yes (Y)'   | System | 27 Sep 2020 20:21:10 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:05', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' | System | 27 Sep 2020 20:21:10 |
| User entered '98.7'  | System | 27 Sep 2020 20:21:10 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:20:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' | System | 27 Sep 2020 20:21:10 |
| User entered 'No (N)'  | System | 27 Sep 2020 20:21:10 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' | System | 27 Sep 2020 20:21:10 |
| User entered '27 Sep 2020 15:21'   | System | 27 Sep 2020 20:21:10 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 3' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:07', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'bdb89629-8e9e-4fbd-aafc-c0c8b85fe0c3' | System | 28 Sep 2020 21:31:19 |
| User entered 'No (N)'  | System | 28 Sep 2020 21:31:19 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'bdb89629-8e9e-4fbd-aafc-c0c8b85fe0c3' | System | 28 Sep 2020 21:31:19 |
| User entered 'No (N)'  | System | 28 Sep 2020 21:31:19 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:16', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'bdb89629-8e9e-4fbd-aafc-c0c8b85fe0c3' | System | 28 Sep 2020 21:31:19 |
| User entered '28 Sep 2020 16:31'   | System | 28 Sep 2020 21:31:19 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 4' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:14', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' | System | 29 Sep 2020 17:00:36 |
| User entered 'Yes (Y)'   | System | 29 Sep 2020 17:00:36 |



US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:24', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' User entered '98.7' | System | 29 Sep 2020 17:00:36 |
|  | System | 29 Sep 2020 17:00:36 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:27', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' | System | 29 Sep 2020 17:00:36 |
| User entered 'No (N)'  | System | 29 Sep 2020 17:00:36 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' | System | 29 Sep 2020 17:00:36 |
| User entered '29 Sep 2020 12:00'   | System | 29 Sep 2020 17:00:36 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 5' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' | System | 01 Oct 2020 03:00:30 |
| User entered 'Yes (Y)'   | System | 01 Oct 2020 03:00:30 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

Please record your **TEMPERATURE** in °F

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' | System | 01 Oct 2020 03:00:30 |
| User entered '98.3'  | System | 01 Oct 2020 03:00:30 |



US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' | System | 01 Oct 2020 03:00:30 |
| User entered 'No (N)'  | System | 01 Oct 2020 03:00:30 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' | System | 01 Oct 2020 03:00:30 |
| User entered '30 Sep 2020 22:00'   | System | 01 Oct 2020 03:00:30 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 6' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:22', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522e0d5-0da7-401d-8f98-0d3b26043153' | System | 02 Oct 2020 14:41:33 |
| User entered 'No (N)'  | System | 02 Oct 2020 14:41:33 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:24', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522e0d5-0da7-401d-8f98-0d3b26043153' | System | 02 Oct 2020 14:41:33 |
| User entered 'No (N)'  | System | 02 Oct 2020 14:41:33 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522e0d5-0da7-401d-8f98-0d3b26043153' | System | 02 Oct 2020 14:41:33 |
| User entered '02 Oct 2020 09:41'   | System | 02 Oct 2020 14:41:33 |



US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 7' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:53

Was **TEMPERATURE** taken?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T23:59:43', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '54bf0452-f158-47fb-9ca6-7937a44a8df5' | System | 03 Oct 2020 05:00:07 |
| User entered 'No (N)'  | System | 03 Oct 2020 05:00:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T23:59:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '54bf0452-f158-47fb-9ca6-7937a44a8df5' | System | 03 Oct 2020 05:00:07 |
| User entered 'No (N)'  | System | 03 Oct 2020 05:00:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T23:59:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '54bf0452-f158-47fb-9ca6-7937a44a8df5' | System | 03 Oct 2020 05:00:07 |
| User entered '02 Oct 2020 23:59'   | System | 03 Oct 2020 05:00:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' | System | 26 Sep 2020 17:53:16 |
| User entered 'None (1)'  | System | 26 Sep 2020 17:53:16 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' | System | 26 Sep 2020 17:53:16 |
| User entered 'No (N)'  | System | 26 Sep 2020 17:53:16 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' | System | 26 Sep 2020 17:53:16 |
| User entered 'No (N)'  | System | 26 Sep 2020 17:53:16 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' | System | 26 Sep 2020 17:53:16 |
| User entered 'None (1)'  | System | 26 Sep 2020 17:53:16 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' | System | 26 Sep 2020 17:53:16 |
| User entered '26 Sep 2020 12:53'   | System | 26 Sep 2020 17:53:16 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:38' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 15:08' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' | System | 27 Sep 2020 14:10:18 |
| User entered 'None (1)'  | System | 27 Sep 2020 14:10:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' | System | 27 Sep 2020 14:10:18 |
| User entered 'No (N)'  | System | 27 Sep 2020 14:10:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' | System | 27 Sep 2020 14:10:18 |
| User entered 'No (N)'  | System | 27 Sep 2020 14:10:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:10', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' User entered 'None (1)' | System | 27 Sep 2020 14:10:18 |
|  | System | 27 Sep 2020 14:10:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:13', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' User entered '27 Sep 2020 09:10' | System | 27 Sep 2020 14:10:18 |
|   | System | 27 Sep 2020 14:10:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 16:03' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 2' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:41', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' | System | 27 Sep 2020 20:21:58 |
| User entered 'Does not interfere with activity (2)'  | System | 27 Sep 2020 20:21:58 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' | System | 27 Sep 2020 20:21:58 |
| User entered 'No (N)'  | System | 27 Sep 2020 20:21:58 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' | System | 27 Sep 2020 20:21:58 |
| User entered 'No (N)'  | System | 27 Sep 2020 20:21:58 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:51', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' | System | 27 Sep 2020 20:21:58 |
| User entered 'None (1)'  | System | 27 Sep 2020 20:21:58 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' | System | 27 Sep 2020 20:21:58 |
| User entered '27 Sep 2020 15:21'   | System | 27 Sep 2020 20:21:58 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 3' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' | System | 28 Sep 2020 21:31:45 |
| User entered 'Does not interfere with activity (2)'  | System | 28 Sep 2020 21:31:45 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' | System | 28 Sep 2020 21:31:45 |
| User entered 'No (N)'  | System | 28 Sep 2020 21:31:45 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:36', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' | System | 28 Sep 2020 21:31:45 |
| User entered 'No (N)'  | System | 28 Sep 2020 21:31:45 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:39', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' | System | 28 Sep 2020 21:31:45 |
| User entered 'None (1)'  | System | 28 Sep 2020 21:31:45 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:42', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' | System | 28 Sep 2020 21:31:45 |
| User entered '28 Sep 2020 16:31'   | System | 28 Sep 2020 21:31:45 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |



**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 4' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' | System | 29 Sep 2020 17:01:18 |
| User entered 'None (1)'  | System | 29 Sep 2020 17:01:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:53', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' | System | 29 Sep 2020 17:01:18 |
| User entered 'No (N)'  | System | 29 Sep 2020 17:01:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' | System | 29 Sep 2020 17:01:18 |
| User entered 'No (N)'  | System | 29 Sep 2020 17:01:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:58', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' | System | 29 Sep 2020 17:01:18 |
| User entered 'None (1)'  | System | 29 Sep 2020 17:01:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' | System | 29 Sep 2020 17:01:18 |
| User entered '29 Sep 2020 12:01'   | System | 29 Sep 2020 17:01:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 5' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:37', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972' | System | 01 Oct 2020 03:01:30 |
| User entered 'None (1)'  | System | 01 Oct 2020 03:01:30 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:42', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972' | System | 01 Oct 2020 03:01:30 |
| User entered 'No (N)'  | System | 01 Oct 2020 03:01:30 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972' | System | 01 Oct 2020 03:01:30 |
| User entered 'No (N)'  | System | 01 Oct 2020 03:01:30 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:53', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972' | System | 01 Oct 2020 03:01:30 |
| User entered 'None (1)'  | System | 01 Oct 2020 03:01:30 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972' | System | 01 Oct 2020 03:01:30 |
| User entered '30 Sep 2020 22:01'   | System | 01 Oct 2020 03:01:30 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 6' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:31', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' | System | 02 Oct 2020 14:41:44 |
| User entered 'None (1)'  | System | 02 Oct 2020 14:41:44 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' | System | 02 Oct 2020 14:41:44 |
| User entered 'No (N)'  | System | 02 Oct 2020 14:41:44 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:36', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' | System | 02 Oct 2020 14:41:44 |
| User entered 'No (N)'  | System | 02 Oct 2020 14:41:44 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' User entered 'None (1)' | System | 02 Oct 2020 14:41:44 |
|  | System | 02 Oct 2020 14:41:44 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' | System | 02 Oct 2020 14:41:44 |
| User entered '02 Oct 2020 09:41'   | System | 02 Oct 2020 14:41:44 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 7' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' | System | 03 Oct 2020 05:00:40 |
| User entered 'None (1)'  | System | 03 Oct 2020 05:00:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

Is there any REDNESS AT INJECTION SITE?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' | System | 03 Oct 2020 05:00:40 |
| User entered 'No (N)'  | System | 03 Oct 2020 05:00:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

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

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:11', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' | System | 03 Oct 2020 05:00:40 |
| User entered 'No (N)'  | System | 03 Oct 2020 05:00:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' | System | 03 Oct 2020 05:00:40 |
| User entered 'None (1)'  | System | 03 Oct 2020 05:00:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Time Stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' | System | 03 Oct 2020 05:00:40 |
| User entered '03 Oct 2020 00:00'   | System | 03 Oct 2020 05:00:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:19', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'None (0)'  | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:21', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'None (0)'  | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'None (0)'  | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:26', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'None (0)'  | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:30', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'None (0)'  | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'None (0)'  | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered 'No (N)'  | System | 26 Sep 2020 17:53:46 |



**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:42', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' | System | 26 Sep 2020 17:53:46 |
| User entered '26 Sep 2020 12:53'   | System | 26 Sep 2020 17:53:46 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:38' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 15:08' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Data entry locked.                                | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:18', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered 'None (0)'  | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered 'Some interference with activity (2)'   | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered 'Some interference with activity (2)'   | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'None (0)' | System | 27 Sep 2020 14:10:50 |
|  | System | 27 Sep 2020 14:10:50 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:39', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered 'None (0)'  | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:41', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered 'None (0)'  | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered 'No (N)'  | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' | System | 27 Sep 2020 14:10:50 |
| User entered '27 Sep 2020 09:10'   | System | 27 Sep 2020 14:10:50 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 16:03' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 2' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:53**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'None (0)'  | System | 27 Sep 2020 20:22:47 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'None (0)'  | System | 27 Sep 2020 20:22:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:17', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'No interference with activity (1)'   | System | 27 Sep 2020 20:22:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'No interference with activity (1)'   | System | 27 Sep 2020 20:22:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'None (0)'  | System | 27 Sep 2020 20:22:47 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:53**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'None (0)'  | System | 27 Sep 2020 20:22:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:43', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered 'No (N)'  | System | 27 Sep 2020 20:22:47 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' | System | 27 Sep 2020 20:22:47 |
| User entered '27 Sep 2020 15:22'   | System | 27 Sep 2020 20:22:47 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 3' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'No interference with activity (1)'   | System | 28 Sep 2020 21:32:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:50', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'No interference with activity (1)'   | System | 28 Sep 2020 21:32:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'Some interference with activity (2)'   | System | 28 Sep 2020 21:32:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'No interference with activity (1)'   | System | 28 Sep 2020 21:32:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:05', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System | 28 Sep 2020 21:32:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'No interference with activity (1)'   | System | 28 Sep 2020 21:32:18 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered 'No (N)'  | System | 28 Sep 2020 21:32:18 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:14', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' | System | 28 Sep 2020 21:32:18 |
| User entered '28 Sep 2020 16:32'   | System | 28 Sep 2020 21:32:18 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 4' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'None (0)'  | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'None (0)'  | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:07', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'None (0)'  | System | 29 Sep 2020 17:01:40 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:10', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'None (0)'  | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'None (0)'  | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:14', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'None (0)'  | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:17', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered 'No (N)'  | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:19', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' | System | 29 Sep 2020 17:01:40 |
| User entered '29 Sep 2020 12:01'   | System | 29 Sep 2020 17:01:40 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 5' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' | System | 01 Oct 2020 03:01:59 |
| User entered 'None (0)'  | System | 01 Oct 2020 03:01:59 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)' | System | 01 Oct 2020 03:01:59 |
|  | System | 01 Oct 2020 03:01:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' | System | 01 Oct 2020 03:01:59 |
| User entered 'None (0)'  | System | 01 Oct 2020 03:01:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)' | System | 01 Oct 2020 03:01:59 |
|  | System | 01 Oct 2020 03:01:59 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:49', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' | System | 01 Oct 2020 03:01:59 |
| User entered 'None (0)'  | System | 01 Oct 2020 03:01:59 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:51', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' | System | 01 Oct 2020 03:01:59 |
| User entered 'None (0)'  | System | 01 Oct 2020 03:01:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' | System | 01 Oct 2020 03:01:59 |
| User entered 'No (N)'  | System | 01 Oct 2020 03:01:59 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:53**

[PC Time stamp](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:58', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered '30 Sep 2020 22:01' | System | 01 Oct 2020 03:01:59 |
|   | System | 01 Oct 2020 03:01:59 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 6' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:43', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'None (0)'  | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'None (0)'  | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:46', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'None (0)'  | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'None (0)'  | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:50', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'None (0)'  | System | 02 Oct 2020 14:41:59 |



**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:53**

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:52', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'None (0)'  | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered 'No (N)'  | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Time stamp](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:57', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' | System | 02 Oct 2020 14:41:59 |
| User entered '02 Oct 2020 09:41'   | System | 02 Oct 2020 14:41:59 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Sep 2020 17:24:07 |
| User entered 'Day 7' | System | 26 Sep 2020 17:24:07 |

**US3342286**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:53**

**HEADACHE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)' | System | 03 Oct 2020 05:01:37 |
|  | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**FATIGUE**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)' | System | 03 Oct 2020 05:01:37 |
|  | System | 03 Oct 2020 05:01:37 |



US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)' | System | 03 Oct 2020 05:01:37 |
|  | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)' | System | 03 Oct 2020 05:01:37 |
|  | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**NAUSEA/VOMITING**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)' | System | 03 Oct 2020 05:01:37 |
|  | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

**CHILLS**

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:18', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)' | System | 03 Oct 2020 05:01:37 |
|  | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:30', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' | System | 03 Oct 2020 05:01:37 |
| User entered 'No (N)'  | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Time stamp](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered '03 Oct 2020 00:01' | System | 03 Oct 2020 05:01:37 |
|   | System | 03 Oct 2020 05:01:37 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Oct 2020 12:00' | System | 26 Sep 2020 17:24:07 |

US3342286

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:53

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Oct 2020 11:59' | System | 26 Sep 2020 17:24:07 |



US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Oct 2020 19:38:52 |

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '5 Oct 2020' | (b) (4), (b) (6) | 05 Oct 2020 19:38:52 |

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 05 Oct 2020 19:38:52 |

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 05 Oct 2020 19:38:52 |
|                     |                  |                      |

US3342286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Oct 2020 19:38:44 |
|                        |                  |                      |

US3342286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Oct 2020 19:38:44 |

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 18:49:45 |

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 12 Oct 2020 18:49:45 |
|                            |                  |                      |



US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 12 Oct 2020 18:49:45 |

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 12 Oct 2020 18:49:45 |
|                     |                  |                      |

US3342286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 18:49:51 |
|                        |                  |                      |

US3342286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 12 Oct 2020 18:49:51 |

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 21:31:03 |
|                        |                  |                      |

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 21:31:03 |
|                            |                  |                      |

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 19 Oct 2020 21:31:03 |
|  |                  |                      |

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 21:31:03 |
|                     |                  |                      |



US3342286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 21:31:09 |
|                        |                  |                      |

US3342286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Oct 2020 21:31:09 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

[Was this visit performed?](#)

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 26 Oct 2020 20:38:41 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '26 Oct 2020' | John Luna (b) (4) | 26 Oct 2020 20:38:41 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                          | User              | Time (GMT)           |
|--------------------------------|-------------------|----------------------|
| User entered 'Clinic (Clinic)' | John Luna (b) (4) | 26 Oct 2020 20:38:41 |

**US3342286**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:53**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 26 Oct 2020 20:38:41 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Timepoint](#)

| Audit  | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Were vital signs assessed?

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '26 Oct 2020' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                | User              | Time (GMT)           |
|----------------------|-------------------|----------------------|
| User entered '13:50' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 13:50' | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered '98.3' F | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered 'Oral (Oral)' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit             | User              | Time (GMT)           |
|-------------------|-------------------|----------------------|
| User entered '83' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Oct 2020 20:39:33 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit             | User              | Time (GMT)           |
|-------------------|-------------------|----------------------|
| User entered '12' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit              | User              | Time (GMT)           |
|--------------------|-------------------|----------------------|
| User entered '181' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

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)  | 27 Oct 2020 16:05:15 |
| 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 'CS per investigator. Subject discontinued from treatment and will follow up with PCP and continue all other study assessments per protocol.' (Site from System). | John Luna (b) (4) | 26 Oct 2020 20:40:38 |
| 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).  |                   | 26 Oct 2020 20:39:33 |
| User entered '127'   | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:53

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Timepoint](#)

| Audit  | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Were vital signs assessed?

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered 'No (N)' | John Luna (b) (4) | 26 Oct 2020 20:39:33 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:39:33 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

Diastolic Blood Pressure (xxx)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:53

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:39:33 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 26 Oct 2020 20:40:46 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Date of examination (*dd MMM yyyy*)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '26 Oct 2020' | John Luna (b) (4) | 26 Oct 2020 20:40:46 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

[Was study treatment given?](#)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered 'No (N)' | John Luna (b) (4) | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

If No, reason not given

| Audit   | User              | Time (GMT)           |
|---|-------------------|----------------------|
| User entered 'Physician withheld dose due to Adverse<br>Event (PHYSICIAN AE)' | John Luna (b) (4) | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

[What was the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

What was the treatment date? (dd MMM yyyy)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

Which arm was used to give treatment?

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:41:11 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

What was the frequency of the study treatment dosing?

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:53

What was the route of administration for the study treatment?

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 20:41:11 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:02 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

Collection date (dd MMM yyyy)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 2 Day 29 collection date confirmed as 26-OCT-2020.' (Site from DM). | Andrew Bell (b) (4)<br>(b) (4)    | 12 Nov 2020 15:24:37 |
| User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).  | (b) (4), (b) (6)<br>(b) (4)       | 10 Nov 2020 09:52:09 |
| User entered '26 Oct 2020'  | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:02 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

Collection time (00:00-23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:31' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:02 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 14:31' | System | 28 Oct 2020 18:58:02 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:53

Collection date (*dd MMM yyyy*)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| User entered '26 Oct 2020' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

[Lab Test](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:26 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

[Was the sample collected?](#)

| Audit                  | User                              | Time (GMT)           |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

Collection time (00:00 - 23:59)

| Audit                | User                              | Time (GMT)           |
|----------------------|-----------------------------------|----------------------|
| User entered '14:33' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 14:33' | System | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

[Lab Test](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Morgan Schulle (b) (4) | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

[Was the sample collected?](#)

| Audit                 | User                              | Time (GMT)           |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

Collection time (00:00 - 23:59)

| Audit               | User                              | Time (GMT)           |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Morgan Schulle (b) (4)<br>(b) (4) | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:53

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Oct 2020 18:58:26 |

US3342286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 26 Oct 2020 20:41:24 |



US3342286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 20:41:24 |

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Was Contact Attempted?](#)

| Audit                  | User                             | Time (GMT)           |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Ethan Shotton (b) (4)<br>(b) (4) | 03 Nov 2020 15:31:51 |

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User entered '3 Nov 2020' | Ethan Shotton (b) (4)<br>(b) (4) | 03 Nov 2020 15:31:51 |

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Ethan Shotton (b) (4)<br>(b) (4) | 03 Nov 2020 15:31:51 |

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                             | Time (GMT)           |
|---------------------|----------------------------------|----------------------|
| User entered empty. | Ethan Shotton (b) (4)<br>(b) (4) | 03 Nov 2020 15:31:51 |

US3342286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Nov 2020 16:42:08 |
|                        |                  |                      |

**US3342286**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:53**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Nov 2020 16:42:08 |

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Nov 2020 16:42:19 |



US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| User entered '9 Nov 2020' | (b) (4), (b) (6) | 09 Nov 2020 16:42:19 |
|                           |                  |                      |

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 09 Nov 2020 16:42:19 |

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 09 Nov 2020 16:42:19 |
|                     |                  |                      |

US3342286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Nov 2020 16:42:23 |
|                        |                  |                      |

US3342286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Nov 2020 16:42:23 |

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 21:56:47 |
|                        |                  |                      |

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '16 Nov 2020' | (b) (4), (b) (6) | 16 Nov 2020 21:56:47 |
|                            |                  |                      |

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 16 Nov 2020 21:56:47 |
|  |                  |                      |



US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:53

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 16 Nov 2020 21:56:47 |
|                     |                  |                      |

US3342286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 21:56:52 |
|                        |                  |                      |

**US3342286**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:53**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Nov 2020 21:56:52 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

[Was this visit performed?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:15:53 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:15:53 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:53

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

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:15:53 |

**US3342286**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:53**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 20 Nov 2020 18:15:53 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Were vital signs assessed?

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |



US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                | User                               | Time (GMT)           |
|----------------------|------------------------------------|----------------------|
| User entered '08:46' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Nov 2020 08:46' | System | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered '98.6' F | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (Oral)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit             | User                               | Time (GMT)           |
|-------------------|------------------------------------|----------------------|
| User entered '80' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

**US3342286**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:53**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Nov 2020 18:16:25 |



US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit             | User                               | Time (GMT)           |
|-------------------|------------------------------------|----------------------|
| User entered '14' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit              | User                               | Time (GMT)           |
|--------------------|------------------------------------|----------------------|
| User entered '174' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Diastolic Blood Pressure (xxx)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).   | (b) (4), (b) (6)        | 23 Nov 2020 13:27:24 |
| Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pt has ongoing AE for unspecified htn' (Site from System). | Darrell O'Brien (b) (4) | 20 Nov 2020 18:16:54 |
| User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).                                    |                         | 20 Nov 2020 18:16:25 |
| User entered '109'   | Darrell O'Brien (b) (4) | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Nov 2020 18:16:25 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Was the physical examination performed?

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:20:37 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Date of examination (*dd MMM yyyy*)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '20 Nov 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:20:37 |



US3342286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

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

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 18:19:09 |

US3342286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:53

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Nov 2020 18:19:09 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '23 Nov 2020 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '27 Nov 2020 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '30 Nov 2020 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Dec 2020 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Dec 2020 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Dec 2020 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Dec 2020 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Dec 2020 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Dec 2020 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Dec 2020 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Dec 2020 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Jan 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Jan 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Jan 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Jan 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Jan 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Jan 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Jan 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Jan 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Jan 2021 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Feb 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Feb 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Feb 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Feb 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Feb 2021 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Feb 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Feb 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Feb 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Mar 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Mar 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Mar 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Mar 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Mar 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Mar 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Mar 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Mar 2021 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Mar 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '02 Apr 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Apr 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '09 Apr 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Apr 2021 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '16 Apr 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Apr 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '23 Apr 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Apr 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '30 Apr 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '03 May 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 May 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '10 May 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 May 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '17 May 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 May 2021 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '24 May 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 May 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '31 May 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Jun 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Jun 2021 00:01' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Jun 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Jun 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Jun 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Jun 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Jun 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Jun 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '02 Jul 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Jul 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '09 Jul 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Jul 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '16 Jul 2021 23:59' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Jul 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '23 Jul 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Jul 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '30 Jul 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '02 Aug 2021 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '06 Aug 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '09 Aug 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '13 Aug 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '16 Aug 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '20 Aug 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '23 Aug 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '27 Aug 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '30 Aug 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '03 Sep 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '06 Sep 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '10 Sep 2021 23:59' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '13 Sep 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '17 Sep 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '20 Sep 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '24 Sep 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '27 Sep 2021 00:01' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Oct 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Oct 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Oct 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Oct 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Oct 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Oct 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Oct 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Oct 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Oct 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Nov 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Nov 2021 23:59' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Nov 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Nov 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Nov 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Nov 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Nov 2021 00:01' | System | 20 Nov 2020 10:57:51 |



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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Nov 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Nov 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '03 Dec 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '06 Dec 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '10 Dec 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '13 Dec 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '17 Dec 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

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**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '20 Dec 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '24 Dec 2021 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '27 Dec 2021 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '31 Dec 2021 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '03 Jan 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Jan 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '10 Jan 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Jan 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '17 Jan 2022 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Jan 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '24 Jan 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Jan 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '31 Jan 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Feb 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Feb 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Feb 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Feb 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Feb 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Feb 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Feb 2022 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Feb 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Mar 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Mar 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Mar 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Mar 2022 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Mar 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Mar 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Mar 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Mar 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Apr 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Apr 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Apr 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Apr 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Apr 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Apr 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Apr 2022 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Apr 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Apr 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '02 May 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '06 May 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '09 May 2022 00:01' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '13 May 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '16 May 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '20 May 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '23 May 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '27 May 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '30 May 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '03 Jun 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '06 Jun 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '10 Jun 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '13 Jun 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '17 Jun 2022 23:59' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '20 Jun 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '24 Jun 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '27 Jun 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Jul 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Jul 2022 00:01' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Jul 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Jul 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Jul 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Jul 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Jul 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Jul 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Jul 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '01 Aug 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Aug 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '08 Aug 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Aug 2022 23:59' | System | 20 Nov 2020 10:57:51 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '15 Aug 2022 00:01' | System | 20 Nov 2020 10:57:51 |

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Aug 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '22 Aug 2022 00:01' | System | 20 Nov 2020 10:57:51 |

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Aug 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '29 Aug 2022 00:01' | System | 20 Nov 2020 10:57:51 |



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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '02 Sep 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '05 Sep 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '09 Sep 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 10:57:51 |

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '12 Sep 2022 00:01' | System | 20 Nov 2020 10:57:51 |

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '16 Sep 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 10:57:51 |



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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '19 Sep 2022 00:01' | System | 20 Nov 2020 10:57:51 |

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '23 Sep 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

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**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 10:57:51 |

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

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**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '26 Sep 2022 00:01' | System | 20 Nov 2020 10:57:51 |

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

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '30 Sep 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '03 Oct 2022 00:01' | System | 20 Nov 2020 10:57:51 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Oct 2022 23:59' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '10 Oct 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Oct 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '17 Oct 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Oct 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '24 Oct 2022 00:01' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Oct 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '31 Oct 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '04 Nov 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '07 Nov 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '11 Nov 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 10:57:51 |



**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '14 Nov 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '18 Nov 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '21 Nov 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '25 Nov 2022 23:59' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '28 Nov 2022 00:01' | System | 20 Nov 2020 10:57:51 |

**US3342286**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:53**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 10:57:51 |
| Amendment Manager: User entered '02 Dec 2022 23:59' | System | 20 Nov 2020 10:57:51 |



US3342286

**Folder: Unscheduled 21 Oct 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 26 Nov 2020 10:57:53**

[Visit Date](#)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '21 Oct 2020' | John Luna (b) (4) | 26 Oct 2020 20:42:13 |

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **26 Nov 2020 10:57:53**

[Physical Exam](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '1' | John Luna (b) (4) | 26 Oct 2020 20:42:13 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:57:53

[Vital Signs](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '1' | John Luna (b) (4) | 26 Oct 2020 20:42:13 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:57:53

[Immunogenicity Assessment](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 26 Oct 2020 20:42:13 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 26 Nov 2020 10:57:53

[Pregnancy Test](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 26 Oct 2020 20:42:13 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Were vital signs assessed?](#)

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Date of assessment (*dd MMM yyyy*)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '21 Oct 2020' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:57:53**

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

| Audit                | User              | Time (GMT)           |
|----------------------|-------------------|----------------------|
| User entered '13:27' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |



US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:57:53**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '21 Oct 2020 13:27' | System | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Temperature (xxx.x)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered '98.3' F | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Route of measurement](#)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered 'Oral (Oral)' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[If Other, specify](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Pulse \(xxx\)](#)

| Audit             | User              | Time (GMT)           |
|-------------------|-------------------|----------------------|
| User entered '63' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

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

| Audit             | User              | Time (GMT)           |
|-------------------|-------------------|----------------------|
| User entered '14' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Oct 2020 20:42:49 |



US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Systolic Blood Pressure (xxx)

| Audit              | User              | Time (GMT)           |
|--------------------|-------------------|----------------------|
| User entered '165' | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:57:53**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:53

Diastolic Blood Pressure (xxx)

| Audit  | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).   | (b) (4), (b) (6)  | 27 Oct 2020 16:05:39 |
| Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject to follow up with PCP per investigator.' (Site from System). | John Luna (b) (4) | 26 Oct 2020 20:43:36 |
| User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).  |                   | 26 Oct 2020 20:42:49 |
| User entered '109'   | John Luna (b) (4) | 26 Oct 2020 20:42:49 |

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Vital Signs**

Generated On: **26 Nov 2020 10:57:53**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Oct 2020 20:42:49 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

[Was the physical examination performed?](#)

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 26 Oct 2020 20:43:43 |

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:53

Date of examination (*dd MMM yyyy*)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '21 Oct 2020' | John Luna (b) (4) | 26 Oct 2020 20:43:43 |

US3342286

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:53

[Did the participant experience any adverse events?](#)

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 22 Oct 2020 19:20:29 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension NOS - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 22 Oct 2020 21:27:19 |
| 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 21:27:19 |
| Data point term sent to Coder  | System                          | 22 Oct 2020 19:22:48 |
| User entered 'Hypertension (Unspecified)'  | John Luna (b) (4)               | 22 Oct 2020 19:21:48 |



US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Was this a medically-attended AE?](#)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered 'No (N)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered 'No (N)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered 'No (N)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

Start date (*dd MMM yyyy*)

| Audit                      | User              | Time (GMT)           |
|----------------------------|-------------------|----------------------|
| User entered '21 Oct 2020' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

Start time (00:00-23:59)

| Audit   | User              | Time (GMT)           |
|---|-------------------|----------------------|
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                    | System            | 22 Oct 2020 19:22:12 |
| User entered empty; reason for change Data Entry Error  | John Luna (b) (4) | 22 Oct 2020 19:22:12 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'data corrected' (Site from System). | John Luna (b) (4) | 22 Oct 2020 19:22:05 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).                    | System            | 22 Oct 2020 19:21:48 |
| User entered '13:27'  | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[AE start date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 22 Oct 2020 19:22:12 |
| User entered '21 Oct 2020 13:27' | System | 22 Oct 2020 19:21:48 |

**US3342286**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Ongoing?](#)

| Audit                  | User              | Time (GMT)           |
|------------------------|-------------------|----------------------|
| User entered 'Yes (Y)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

If not Ongoing, end date (*dd MMM yyyy*)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |



US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[End time \(00:00-23:59\)](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

**US3342286**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:57:53**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Severity](#)

| Audit  | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Is the adverse event serious?](#)

| Audit                 | User              | Time (GMT)           |
|-----------------------|-------------------|----------------------|
| User entered 'No (N)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Death](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Life threatening](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

Hospital Admission Date (*dd MMM yyyy*)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |



US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

Hospital Discharge Date (*dd MMM yyyy*)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

**US3342286**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Admitted to ICU?](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Number of Days in ICU](#)

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Persistent or significant disability or incapacity](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Congenital anomaly or birth defect](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Other medically important event](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Relationship to investigational product](#)

| Audit                                    | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Relationship to Study Procedure](#)

| Audit                                    | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |



US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Action taken with investigational product](#)

| Audit                                      | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User entered 'Dose Delayed (DOSE DELAYED)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[None](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered 'I' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Concomitant Medication](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Concomitant Procedure](#)

| Audit            | User              | Time (GMT)           |
|------------------|-------------------|----------------------|
| User entered '0' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Outcome](#)

| Audit  | User              | Time (GMT)           |
|--|-------------------|----------------------|
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 26 Nov 2020 10:57:53

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

| Audit               | User              | Time (GMT)           |
|---------------------|-------------------|----------------------|
| User entered empty. | John Luna (b) (4) | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Narrative](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User entered 'CALLED PT TO F/U ON ELEVATED BP. PT DID NOT ANSWER, BUT PI LEFT DETAILED VOICEMAIL. REMINDED PT OF VISIT AND RECOMMENDATION HE SEE A PCP RE: BP. THIS RECOMMENDATION WAS REITERATED BY DR. PICKRELL AT A SUBSEQUENT VISIT. PI OFFERED THAT WE HAVE A LIST OF ACCESSIBLE CLINICS IN CASE PT IN UNABLE TO SEE HIS WIFE'S MD AS HE HOPED. PI SPECIFICALLY MENTIONED LONE STAR CIRCLE OF CARE, WHICH HAS LOCATIONS IN TRAVIS AND WILLIAMSON COUNTIES. LIST OBTAINED FROM CITY OF AUSTIN WEBSITE, WHICH PI REFERENCED TO HIM. (b) (6) 02NOV2020. | Darrell O'Brien (b) (4) | 20 Nov 2020 18:21:41 |

UPDATE: AT PT VISIT 3 (20NOV20230) PT WAS ASKED IF HE F/U WITH PCP/MEDICAL PROVIDER REGARDING ELEVATED BP. PT STATED THAT HE HAD NOT FOLLOWED UP WITH ANYONE IRT THE ELEVATED BP. PT STILL INTENDS ON SEEING MEDICAL PROVIDER (SPECIFICALLY STATING "LONE STAR") AFTER THANKSGIVING. HE WAS INFORMED THAT HE WOULD BE ABLE TO HAVE AN APPOINTMENT AT THAT TIME. PT NEEDS TO CALL CLINIC IN ORDER TO SCHEDULED APPOINTMENT AFTER THANKSGIVING. WILL F/U WITH PT AND MONITOR FOR ADDITIONAL INFORMATION. due to patient's elevated bp at visit 3, sx directed physical conducted focused on cardiovascular assessment. DAO 20NOV2020.' reason for change: New Information

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Narrative](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User entered 'Called pt to f/u on elevated BP. Pt did not answer, but PI left detailed voicemail. Reminded pt of visit and recommendation he see a PCP re: BP. This recommendation was reiterated by Dr. Pickrell at a subsequent visit. PI offered that we have a list of accessible clinics in case pt in unable to see his wife's MD as he hoped. PI specifically mentioned lone star circle of care, which has locations in Travis and Williamson Counties. List obtained from city of austin website, which PI referenced to him. (b) (6) (b) (6) 02NOV2020.<br /><br />Update: at pt Visit 3 (20NOV20230) pt was asked if he f/u with pcp/medical provider regarding elevated bp. Pt stated that he had not followed up with anyone irt the elevated bp. Pt still intends on seeing medical provider (specifically stating "lone star") after Thanksgiving. He was informed that he would be able to have an appointment at that time. Pt needs to call clinic in order to scheduled appointment after Thanksgiving. Will f/u with pt and monitor for additional information. DAO 20NOV2020.' reason for change: Data Entry Error | Darrell O'Brien (b) (4) (b) (4) | 20 Nov 2020 18:01:35 |
| User entered empty.   | John Luna (b) (4)               | 22 Oct 2020 19:21:48 |



US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Oct 2020 19:21:48 |

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Oct 2020 19:21:48 |

US3342286

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

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

**Generated On: 26 Nov 2020 10:57:53**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:04:21 |

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:53

[Name of Medication](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)    | 26 Sep 2020 17:06:45 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)    | 26 Sep 2020 17:06:45 |
| Data point term sent to Coder   | System                  | 26 Sep 2020 17:06:04 |
| User entered 'Diphenhydramine'  | Darrell O'Brien (b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Indication](#)

| Audit                             | User                               | Time (GMT)           |
|-----------------------------------|------------------------------------|----------------------|
| User entered 'Seasonal Allergies' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Dose per administration](#)

| Audit             | User                               | Time (GMT)           |
|-------------------|------------------------------------|----------------------|
| User entered '50' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'mg (mg)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |



US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

If dose unit is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| User entered 'as needed (PRN)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

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

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |



US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:05:04 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:57:53**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:05:04 |

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:53

[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-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)    | 26 Sep 2020 17:06:45 |
| 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)    | 26 Sep 2020 17:06:45 |
| Data point term sent to Coder  | System                             | 26 Sep 2020 17:06:04 |
| User entered 'Ibuprofen'   | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Prophylaxis](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Indication](#)

| Audit                           | User                               | Time (GMT)           |
|---------------------------------|------------------------------------|----------------------|
| User entered 'Generalized Pain' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |



US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Dose per administration](#)

| Audit              | User                               | Time (GMT)           |
|--------------------|------------------------------------|----------------------|
| User entered '200' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Dose unit](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'mg (mg)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

If dose unit is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Frequency](#)

| Audit                          | User                               | Time (GMT)           |
|--------------------------------|------------------------------------|----------------------|
| User entered 'as needed (PRN)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[If frequency is Other, specify](#)

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Route of administration](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

If route of administration is Other, specify

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2000' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |



US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Start date completely unknown](#)

| Audit            | User                               | Time (GMT)           |
|------------------|------------------------------------|----------------------|
| User entered '0' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Ongoing?](#)

| Audit                  | User                               | Time (GMT)           |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit               | User                               | Time (GMT)           |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Was this medication taken for solicited event?](#)

| Audit                 | User                               | Time (GMT)           |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Darrell O'Brien (b) (4)<br>(b) (4) | 26 Sep 2020 17:05:37 |

US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:05:37 |

US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:05:37 |

US3342286

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:53**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Sep 2020 17:05:37 |

US3342286

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:53

Date of dosing discontinuation (dd MMM yyyy)

| Audit                      | User                               | Time (GMT)           |
|----------------------------|------------------------------------|----------------------|
| User entered '21 Oct 2020' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:50:15 |



US3342286

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:53

[Primary reason for dosing discontinuation](#)

| Audit                                       | User                               | Time (GMT)           |
|---|------------------------------------|----------------------|
| User entered 'AE (specify) (ADVERSE EVENT)' | Darrell O'Brien (b) (4)<br>(b) (4) | 20 Nov 2020 20:50:15 |

US3342286

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 26 Nov 2020 10:57:53**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM). | (b) (4), (b) (6)        | 23 Nov 2020 01:46:16 |
| User entered 'AE: Hypertension, unspecified.'  | Darrell O'Brien (b) (4) | 20 Nov 2020 20:50:15 |