

US3302384 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:50:35

All time stamps listed in this document are displayed in GMT

**US3302384**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:50:35**

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[Participant ID](#)

US3302384

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

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US3302384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 26 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | SCRN                                    |

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

|                                           |                                                                                                                                                                            |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy)                  | (b) (6) 1997                                                                                                                                                               |
| Age                                       | 22                                                                                                                                                                         |
| Age Units                                 | YEARS                                                                                                                                                                      |
| Age (Derived)                             | 22                                                                                                                                                                         |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>                                                                                                      |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |                                                                                                                                                                            |
| White                                     | True                                                                                                                                                                       |
| Black                                     | False                                                                                                                                                                      |
| Asian                                     | False                                                                                                                                                                      |
| American Indian or Alaska Native          | False                                                                                                                                                                      |
| Native Hawaiian or other Pacific Islander | False                                                                                                                                                                      |
| Other                                     | False                                                                                                                                                                      |
| If race is Other, specify _____           |                                                                                                                                                                            |
| Unknown                                   | False                                                                                                                                                                      |
| Not reported                              | False                                                                                                                                                                      |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:35

|                                                 |                                              |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 26 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020                                         |
| Protocol Version                                | Amendment 1 <input type="radio"/>            |
|                                                 | Amendment 2 <input type="radio"/>            |
|                                                 | Amendment 3 <input checked="" type="radio"/> |
|                                                 | Amendment 4 <input type="radio"/>            |
|                                                 | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|                                                 | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|                                                 | Inclusion/Exclusion <input type="radio"/>    |
|                                                 | Cohort Full <input type="radio"/>            |
|                                                 | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |                                              |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|                                                 | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |                                              |
| Enrollment Trigger                              | 1                                            |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:50:35

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 10:50:35**

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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 10:50:35

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | ANXIETY                                                          |
| Start date (dd MMM yyyy)                                | UN MAY 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)                          | MAY 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 10:50:35

|                                                   |                                                                  |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition                                         | DEPRESSION                                                       |
| Start date (dd MMM yyyy)                          | UN MAY 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)                    | MAY 2020                                                         |
| Start Year (derived)                              | 2020                                                             |
| Stop Month and Year (derived)                     |                                                                  |
| Stop Year (derived)                               |                                                                  |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:35

|                                                         |                                                                  |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition                                               | IUD                                                              |
| Start date (dd MMM yyyy)                                | UN UNK 2019                                                      |
| 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 2019                                                         |
| Start Year (derived)                                    | 2019                                                             |
| Stop Month and Year (derived)                           | _____                                                            |
| Stop Year (derived)                                     | _____                                                            |

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

|                                           |                                      |
|-------------------------------------------|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|                                           | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 26 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:45 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 26 AUG 2020 13:45                    |
| Height ( <i>xxx.x</i> )                   | 61 in                                |
| Weight ( <i>xxx.x</i> )                   | 150 lb                               |
| BMI ( <i>xxx.x</i> )                      | 28.40151 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 10:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*) 26 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 26 AUG 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |                                           |
| Collection time                     |                                           |
| Collection date and time (derived)  |                                           |

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

#### Occupational Risk

|                                                                                                                                                         |                                      |                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-------------------------------------|
| <b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)                                            | Yes <input checked="" type="radio"/> | No <input type="radio"/>            |
| <b>Emergency Response</b> (e.g., Law enforcement officers, Firefighters, emergency medical service workers)                                             | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Retail or Restaurant Operations</b> , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Manufacturing &amp; Production Operations</b> with inherent overcrowding (e.g., factory workers, meat/food processing plants)                        | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Warehouse shipping and fulfillment centers</b> and jobs (e.g., Amazon facilities)                                                                    | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Transportation and delivery services</b> (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)                                     | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Border Protection and Military Personnel</b> (e.g., TSA, custom and border protection agents, military personnel not social distancing)              | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Personal Care and in-home services</b> (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)                | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Hospitality and Tourism Workers</b> (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)                                          | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Pastoral, Social or Public Health Workers</b> requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Educators and Students</b> (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)                  | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |
| <b>Other</b>                                                                                                                                            | Yes <input type="radio"/>            | No <input checked="" type="radio"/> |

#### Specify

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

|                                                                                                                                              |       |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------|
| <b>No Risk Identified</b>                                                                                                                    | False |
| <b>Resides in Nursing Home or Assisted Living Facility</b>                                                                                   | False |
| <b>Resides in Multi-family dwelling</b> (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 10:50:35

|                                                                                                                                        |       |
|----------------------------------------------------------------------------------------------------------------------------------------|-------|
| <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) | True  |
| <b>Resides in a single family home</b> (i.e., detached housing)                                                                        | False |
| <b>Other</b>                                                                                                                           | False |
| <b>Specify</b>                                                                                                                         |       |



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 26 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

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

What was the participant's randomization number? 108673

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 10:50:35**

|        |               |
|--------|---------------|
| 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 10:50:35

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 13:45 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 26 AUG 2020 13:45                                                                                      |
| Temperature (xxx.x)                 | 97.7 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 59 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 14 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 109 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 66 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 10:50:35

|                                     |                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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 AUG 2020                                                                                            |
| Time of assessment (00:00-23:59)    | 14:53 (24 HR)                                                                                          |
| Vital Signs Date and Time (derived) | 26 AUG 2020 14:53                                                                                      |
| Temperature (xxx.x)                 | 97.7 F                                                                                                 |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |                                                                                                        |
| Pulse (xxx)                         | 67 beats/min                                                                                           |
| Pulse units                         | BPM                                                                                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                                                                                         |
| Respiratory Rate units              | BREATHS/MIN                                                                                            |
| Systolic Blood Pressure (xxx)       | 116 mmHg                                                                                               |
| Systolic Blood Pressure units       | MMHG                                                                                                   |
| Diastolic Blood Pressure (xxx)      | 72 mmHg                                                                                                |
| Diastolic Blood Pressure units      | MMHG                                                                                                   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

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: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (*dd MMM yyyy*) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

|                                                                                                              |                                                                    |
|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| Was study treatment given?                                                                                   | Yes <input checked="" type="radio"/>                               |
|                                                                                                              | No <input type="radio"/>                                           |
| If No, reason not given                                                                                      | Participant declined due to Adverse Event <input type="radio"/>    |
|                                                                                                              | Physician withheld dose due to Adverse Event <input type="radio"/> |
|                                                                                                              | Death <input type="radio"/>                                        |
|                                                                                                              | Lost To Follow-Up <input type="radio"/>                            |
|                                                                                                              | Physician Decision <input type="radio"/>                           |
|                                                                                                              | Pregnancy <input type="radio"/>                                    |
|                                                                                                              | Protocol Deviation <input type="radio"/>                           |
|                                                                                                              | Study Terminated by Sponsor <input type="radio"/>                  |
|                                                                                                              | Withdrawal of Consent by Participant <input type="radio"/>         |
|                                                                                                              | Confirmed COVID-19 <input type="radio"/>                           |
|                                                                                                              | Other <input type="radio"/>                                        |
| If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify |                                                                    |
| What was the study treatment?                                                                                | MRNA-1273 OR PLACEBO                                               |
| What was the treatment date? (dd MMM yyyy)                                                                   | 26 AUG 2020                                                        |
| What was the treatment time? (00:00-23:59)                                                                   | 14:23 (24 HR)                                                      |
| Treatment Date and Time (derived)                                                                            | 26 AUG 2020 14:23                                                  |
| Which arm was used to give treatment?                                                                        | Left Arm <input checked="" type="radio"/>                          |
|                                                                                                              | Right Arm <input type="radio"/>                                    |
| 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 10:50:35

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 26 AUG 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 13:52 (24 HR)                        |
| Collection date and time (derived)     | 26 AUG 2020 13:52                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:35

|                                        |                           |                                          |                                    |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 26 AUG 2020                        |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 13:50                                    | 26 AUG 2020 13:50                  |
| Nasopharyngeal Swab 2                  | No                        |                                          |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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 10:50:35

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 14:43

PC Open Date & Time

26 AUG 2020 14:43

PC Close Date & Time

26 AUG 2020 17:13

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

**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 98.4 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 27 AUG 2020 08:18 |
| PC Open Date & Time  | 26 AUG 2020 18:08 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:50:35

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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

98.4 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

28 AUG 2020 08:49

---

PC Open Date & Time

27 AUG 2020 12:00

---

PC Close Date & Time

28 AUG 2020 11:59

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US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:50:35

---

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:50:35

---

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 08:51

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:50:35

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 09:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:50:35

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 08:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 14:44

PC Open Date & Time

26 AUG 2020 14:43

PC Close Date & Time

26 AUG 2020 17:13

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

**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 AUG 2020 08:18

PC Open Date & Time

26 AUG 2020 18:08

PC Close Date & Time

27 AUG 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:50:35

**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

28 AUG 2020 08:49

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:50:35

**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 AUG 2020 12:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:50:35

**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

31 AUG 2020 08:51

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:50:35

**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

01 SEP 2020 09:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 08:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

**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 ☐

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 26 AUG 2020 14:45 |
| PC Open Date & Time  | 26 AUG 2020 14:43 |
| PC Close Date & Time | 26 AUG 2020 17:13 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

**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 ☐

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 27 AUG 2020 08:19 |
| PC Open Date & Time  | 26 AUG 2020 18:08 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:50:35

**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 ☒

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:50:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 AUG 2020 08:49 |
| PC Open Date & Time          | 27 AUG 2020 12:00 |
| PC Close Date & Time         | 28 AUG 2020 11:59 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:50:35

**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 ☒



US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:50:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 AUG 2020 12:07 |
| PC Open Date & Time          | 29 AUG 2020 12:00 |
| PC Close Date & Time         | 30 AUG 2020 11:59 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:50:35

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 ☒

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:50:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 31 AUG 2020 08:51 |
| PC Open Date & Time          | 30 AUG 2020 12:00 |
| PC Close Date & Time         | 31 AUG 2020 11:59 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:50:35

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 ☒

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:50:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 SEP 2020 09:19 |
| PC Open Date & Time          | 31 AUG 2020 12:00 |
| PC Close Date & Time         | 01 SEP 2020 11:59 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:50:35

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 ☒

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:50:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 SEP 2020 08:23 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3302384

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 04 SEP 2020 08:17

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59



US3302384

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:50:35

|                                                                                                         |                                                                  |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| <b>TIMEPOINT</b>                                                                                        | DAY 9                                                            |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp                                                                                           | 04 SEP 2020 08:17                                                |
| PC Open Date & Time                                                                                     | 03 SEP 2020 12:00                                                |
| PC Close Date & Time                                                                                    | 04 SEP 2020 11:59                                                |

US3302384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

|                                                                 |                                         |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|                                                                 | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)                                        | 23 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|                                                                 | Clinic <input checked="" type="radio"/> |
| Folder OID                                                      | VISIT2                                  |



US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 23 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 13:30 (24 HR)                             |
| Vital Signs Date and Time (derived) | 23 SEP 2020 13:30                         |
| Temperature (xxx.x)                 | 98.4 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |                                           |
| Pulse (xxx)                         | 79 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 18 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 115 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 82 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

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

US3302384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3302384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

|                                     |                                           |
|-------------------------------------|-------------------------------------------|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 23 SEP 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |                                           |
| Collection time                     |                                           |
| Collection date and time (derived)  |                                           |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

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? \_\_\_\_\_

US3302384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 23 SEP 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 13:42 (24 HR)                        |
| Collection date and time (derived)     | 23 SEP 2020 13:42                    |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:35

| Collection date ( <i>dd MMM yyyy</i> ) |                           |                                          | 23 SEP 2020                        |
|----------------------------------------|---------------------------|------------------------------------------|------------------------------------|
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 13:40                                    | 23 SEP 2020 13:40                  |
| Nasopharyngeal Swab 2                  | Yes                       | 13:40                                    | 23 SEP 2020 13:40                  |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3302384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

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

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

|                                           |                                       |
|-------------------------------------------|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|                                           | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 20 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:20 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 20 OCT 2020 13:20                     |
| Temperature ( <i>xxx.x</i> )              | 99.1 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|                                           | Axillary <input type="radio"/>        |
|                                           | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 84 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 113 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 78 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |



US3302384

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3302384

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

|                                        |                                      |
|----------------------------------------|--------------------------------------|
| Was the sample collected?              | Yes <input checked="" type="radio"/> |
|                                        | No <input type="radio"/>             |
| Collection date ( <i>dd MMM yyyy</i> ) | 20 OCT 2020                          |
| Collection time ( <i>00:00-23:59</i> ) | 13:30 (24 HR)                        |
| Collection date and time (derived)     | 20 OCT 2020 13:30                    |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 07:08:15

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3302384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 20:44:34

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3302384

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 06:34:26

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 61                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 23 OCT 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 OCT 2020 23:59 |



US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 68                                                                                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2020 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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> | 13 NOV 2020 00:01 |
|----------------------------------------------------|-------------------|

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|                                                     |                   |
|-----------------------------------------------------|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 NOV 2020 23:59 |
|-----------------------------------------------------|-------------------|

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 11:44:28

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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27 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

04 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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11 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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15 DEC 2020 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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18 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2020 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 DEC 2020 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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[Patient Cloud Close Date & Time](#)

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05 JAN 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 08 JAN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 12 JAN 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 145                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 152                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

22 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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19 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 187                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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26 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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> | 05 MAR 2021 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 MAR 2021 23:59 |
|-----------------------------------------------------|-------------------|

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 12 MAR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 MAR 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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19 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 222                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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02 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 257                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |



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**Generated On: 26 Nov 2020 10:50:35**

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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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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 11 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JUN 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 JUN 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 313                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="checkbox"/><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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 09 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 JUL 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 355                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 20 AUG 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 AUG 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 03 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 07 SEP 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 390                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 01 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 OCT 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 411                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 OCT 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 05 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 NOV 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 12 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 NOV 2021 23:59 |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 10 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 DEC 2021 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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24 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 DEC 2021 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 495                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="checkbox"/><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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 502                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 537                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="checkbox"/><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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

11 FEB 2022 00:01

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15 FEB 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 544                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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18 FEB 2022 00:01

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22 FEB 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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04 MAR 2022 00:01

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08 MAR 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 MAR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 MAR 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 MAR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 MAR 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 642                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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](#)

10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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 <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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 670                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="checkbox"/><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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 24 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 JUN 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

|                                                                                                                                                           |                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 08 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 12 JUL 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 691                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="checkbox"/><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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 12 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 AUG 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                               |



**US3302384**

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

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**Generated On: 26 Nov 2020 10:50:35**

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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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02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

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

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| 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="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 768                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 775                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="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"/>                                            |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 07 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 11 OCT 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 782                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 14 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 OCT 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

**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 ☐

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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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>  | 21 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 OCT 2022 23:59 |

US3302384

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:35

| TIMEPOINT                                                                                                                                                                       | DAY 796                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?                                              | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>                                               |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):                                                                           |                                                                                                     |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )                                                                                                            | <input type="checkbox"/>                                                                            |
| Chills                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Cough                                                                                                                                                                           | <input type="checkbox"/>                                                                            |
| Shortness of breath                                                                                                                                                             | <input type="checkbox"/>                                                                            |
| Difficulty breathing                                                                                                                                                            | <input type="checkbox"/>                                                                            |
| Fatigue                                                                                                                                                                         | <input type="checkbox"/>                                                                            |
| Muscle aches                                                                                                                                                                    | <input type="checkbox"/>                                                                            |
| Body aches                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Headache                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| New loss of taste                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| New loss of smell                                                                                                                                                               | <input type="checkbox"/>                                                                            |
| Sore throat                                                                                                                                                                     | <input type="checkbox"/>                                                                            |
| Congestion                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Runny nose                                                                                                                                                                      | <input type="checkbox"/>                                                                            |
| Nausea                                                                                                                                                                          | <input type="checkbox"/>                                                                            |
| Vomiting                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Diarrhea                                                                                                                                                                        | <input type="checkbox"/>                                                                            |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?                                        | No <input type="radio"/><br>Yes <input type="radio"/>                                               |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

28 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 NOV 2022 23:59

---

US3302384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

Was Contact Attempted?

Yes ☒

No ☐

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

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3302384

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3302384**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

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*

**US3302384**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3302384**

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

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:50:35**

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

**US3302384**

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

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

**Generated On: 26 Nov 2020 10:50:35**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

**US3302384**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 10:50:35**

---

Did the participant experience any adverse events?

Yes ☐

No ☐

---

**If Yes, enter details on the Adverse Events form.**

---



US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:50:35

---

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

Yes ☒

No ☐

---

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

---

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | LEXAPRO                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ANXIETY/DEPRESSION                                                                                                                                                                                                                                                                                                                                                                                                       |
| Dose per administration        | 5                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

|                                                                   |                          |                                  |
|-------------------------------------------------------------------|--------------------------|----------------------------------|
|                                                                   | 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 MAY 2020              |                                  |
| Start date completely unknown                                     | False                    |                                  |
| Ongoing?                                                          | Yes                      | <input checked="" type="radio"/> |
|                                                                   | No                       | <input type="radio"/>            |
| <hr/>                                                             |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>                                                             |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|                                                                   | No                       | <input checked="" type="radio"/> |
| <hr/>                                                             |                          |                                  |
| Separate Dosage Number (derived)                                  | 1                        |                                  |
| Interval Dosage Unit Number (derived)                             | 1                        |                                  |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|                                                                   | 803                      | <input type="radio"/>            |
|                                                                   | 804                      | <input checked="" type="radio"/> |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name of Medication             | ATIVAN                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>                                                                                                                                                                                                                                                                                                                                                         |
| Indication                     | ANXIETY                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Dose per administration        | 0.5                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>                                                                                                                                         |
| If dose unit is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>                                                                                                                                                                                            |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

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

US3302384

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:50:35

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3302384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:35

Date of dosing discontinuation (dd MMM yyyy)

02 SEP 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 \_\_\_\_\_

US3302384

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:35

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

US3302384 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

**US3302384**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:50:35**

[Participant ID](#)

| Audit                    | User                                            | Time (GMT)           |
|--------------------------|-------------------------------------------------|----------------------|
| User entered 'US3302384' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Aug 2020 17:44:21 |

US3302384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:01 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered '26 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 26 Aug 2020 17:44:22 |

US3302384

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:01 |
|                                |                          |                      |
|                                |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:50:35**

[Folder OID](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 26 Aug 2020 17:58:01 |

US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

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

| Audit                      | User                                           | Time (GMT)           |
|----------------------------|------------------------------------------------|----------------------|
| User entered (b) (6) 1997' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 26 Aug 2020 17:44:24 |

US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

[Age](#)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '22' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                   |                          |                      |
|                   |                          |                      |



**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Age Units](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 26 Aug 2020 17:58:10 |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Age \(Derived\)](#)

| Audit             | User   | Time (GMT)           |
|-------------------|--------|----------------------|
| User entered '22' | System | 26 Aug 2020 17:58:19 |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Sex](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User entered 'Female (F)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                           |                          |                      |
|                           |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Ethnicity](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                                                                |                          |                      |
|                                                                |                          |                      |

US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

White

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '1' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Black](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Asian](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

[American Indian or Alaska Native](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |



US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

[Native Hawaiian or other Pacific Islander](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Other](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

If race is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:35

Unknown

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:50:35**

[Not reported](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:10 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:35

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:19 |
|                            |                          |                      |
|                            |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 26 Aug 2020 17:58:19 |

**US3302384**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 26 Aug 2020 17:58:19 |



**US3302384**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:50:35**

[Protocol Version](#)

| Audit                                                                 | User                                   | Time (GMT)           |
|-----------------------------------------------------------------------|----------------------------------------|----------------------|
| User entered 'Amendment 3 (3)' reason for change:<br>Data Entry Error | Brittany Belcher (b) (4)<br>[REDACTED] | 23 Oct 2020 14:55:38 |
| User entered 'Amendment 1 (1)'                                        | Brittany Belcher (b) (4)<br>[REDACTED] | 26 Aug 2020 17:58:19 |

US3302384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:19 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:50:35**

[If No, indicate reason for screen fail](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:19 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:50:35**

If reason for screen fail is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:19 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:35

[Was this participant screened previously?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:19 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:35

[If Yes, previous participant number](#)

| Audit               | User                                           | Time (GMT)           |
|---------------------|------------------------------------------------|----------------------|
| User entered empty. | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>[REDACTED] | 26 Aug 2020 17:44:22 |

**US3302384**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:50:35**

[Enrollment Trigger](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Aug 2020 17:58:23 |

US3302384

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:50:35

Did the participant meet all eligibility criteria?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:23 |
|                        |                          |                      |
|                        |                          |                      |



US3302384

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:50:35

[Were any significant conditions reported?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:30 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:35

[Condition](#)

| Audit                                                                                                                                                               | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)     | 27 Aug 2020 17:58:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                        | Coder Import (b) (4)     | 27 Aug 2020 17:58:50 |
| Data point term sent to Coder                                                                                                                                       | System                   | 26 Aug 2020 17:59:07 |
| User entered 'anxiety'                                                                                                                                              | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:45 |
|                                                                                                                                                                     |                          |                      |
|                                                                                                                                                                     |                          |                      |

US3302384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'un May 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:45 |
|                            |                          |                      |
|                            |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Start date completely unknown](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:45 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Condition ongoing at study entry](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:45 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:45 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Stop date completely unknown](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:45 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'May 2020' | System | 26 Aug 2020 17:58:45 |



**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 26 Aug 2020 17:58:45 |

**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 17:58:45 |

**US3302384**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 17:58:45 |

US3302384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:35

[Condition](#)

| Audit                                                                                                                                                                                    | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4)     | 27 Aug 2020 17:58:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                             | Coder Import (b) (4)     | 27 Aug 2020 17:58:50 |
| Data point term sent to Coder                                                                                                                                                            | System                   | 26 Aug 2020 17:59:08 |
| User entered 'depression'                                                                                                                                                                | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:57 |
|                                                                                                                                                                                          |                          |                      |
|                                                                                                                                                                                          |                          |                      |

US3302384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'un May 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:57 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:35

Start date completely unknown

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:57 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Condition ongoing at study entry](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:57 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:57 |
|                     |                          |                      |
|                     |                          |                      |



**US3302384**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Stop date completely unknown](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:58:57 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'May 2020' | System | 26 Aug 2020 17:58:57 |

**US3302384**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2020' | System | 26 Aug 2020 17:58:57 |

**US3302384**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 17:58:57 |

**US3302384**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 17:58:57 |

US3302384

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:35

[Condition](#)

| Audit                                                                                                                                                                                                                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Intrauterine contraception, LLT: Intra-uterine contraceptive device - version MedDRA\\23.0. | Coder Import (b) (4)     | 27 Aug 2020 17:58:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.                                                                                                                                                                 | Coder Import (b) (4)     | 27 Aug 2020 17:58:53 |
| Data point term sent to Coder                                                                                                                                                                                                                                | System                   | 26 Aug 2020 18:00:09 |
| User entered 'iud'                                                                                                                                                                                                                                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:09 |
|                                                                                                                                                                                                                                                              |                          |                      |
|                                                                                                                                                                                                                                                              |                          |                      |

US3302384

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'un UNK 2019' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:09 |
|                            |                          |                      |
|                            |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

[Start date completely unknown](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:09 |
|                  |                          |                      |
|                  |                          |                      |



**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

[Condition ongoing at study entry](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:09 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:09 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

[Stop date completely unknown](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:09 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                   | User   | Time (GMT)           |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 26 Aug 2020 17:59:09 |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '2019' | System | 26 Aug 2020 17:59:09 |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 17:59:09 |

**US3302384**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 17:59:09 |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Were vital signs assessed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                        |                          |                      |
|                        |                          |                      |



US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

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

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:45' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 13:45' | System | 26 Aug 2020 17:59:39 |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Height (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User entered '61' in      | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                           |                          |                      |
| DataPoint set to visible. | System                   | 26 Aug 2020 17:58:23 |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User entered '150' lb     | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                           |                          |                      |
| DataPoint set to visible. | System                   | 26 Aug 2020 17:58:23 |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                      | User   | Time (GMT)           |
|--------------------------------------------|--------|----------------------|
| Amendment Manager: User entered '28.40151' | System | 17 Sep 2020 00:04:02 |
| User entered '28.4'                        | System | 26 Aug 2020 17:59:39 |
| DataPoint set to visible.                  | System | 26 Aug 2020 17:58:23 |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[BMI units](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--------|----------------------|
| User entered 'kg/m2'      | System | 26 Aug 2020 17:59:39 |
| DataPoint set to visible. | System | 26 Aug 2020 17:58:23 |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Temperature (xxx.x)

| Audit                                                                                                                                                                                                                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)         | 08 Oct 2020 06:26:04 |
| Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'done' (Site from DM). | Brittany Belcher (b) (4) | 07 Oct 2020 18:58:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                                                                 | Brittany Belcher (b) (4) | 07 Oct 2020 18:58:05 |
| User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).          | (b) (4), (b) (6)         | 30 Sep 2020 13:16:09 |
| User entered '97.7' F                                                                                                                                                                                                                                                       | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |



US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

[Route of measurement](#)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:58:05 |
|                                                        |                          |                      |
| User entered 'Oral (Oral)'                             | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                                                        |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

[Pulse \(xxx\)](#)

| Audit                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:58:05 |
| User entered '59'                                                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Aug 2020 17:59:39 |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:58:05 |
|                                                                             |                          |                      |
| User entered '14'                                                           | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |
|                                                                             |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Aug 2020 17:59:39 |

US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Systolic Blood Pressure (xxx)

| Audit                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:58:05 |
| User entered '109'                                                          | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:39 |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Aug 2020 17:59:39 |



US3302384

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Diastolic Blood Pressure (xxx)

| Audit                                                                          | User                                   | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Brittany Belcher (b) (4)<br>[REDACTED] | 07 Oct 2020 18:58:05 |
| User entered '66'                                                              | Brittany Belcher (b) (4)<br>[REDACTED] | 26 Aug 2020 17:59:39 |

**US3302384**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Aug 2020 17:59:39 |

US3302384

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Was the physical examination performed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:45 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:50:35**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:45 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

[Is the participant of childbearing potential?](#)

| Audit                                                      | User                     | Time (GMT)           |
|------------------------------------------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:02 |
|                                                            |                          |                      |
| User entered 'No (N)'                                      | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                                                            |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

If No, what is the reason?

| Audit                                                                                                                                  | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System). | System                   | 26 Aug 2020 18:00:02 |
| User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System). | System                   | 26 Aug 2020 17:59:56 |
| User entered empty.                                                                                                                    | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                                                                                                                                        |                          |                      |
|                                                                                                                                        |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

If Partner medically sterile or Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                     |                          |                      |
|                     |                          |                      |



US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

Date of surgery unknown

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:50:35

Date of last menstruation unknown

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 17:59:56 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Was the pregnancy test performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

Date of test (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Test performed](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User entered 'Urine (URINE)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                              |                          |                      |
|                              |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Result](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| User entered 'Negative (NEGATIVE)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                                    |                          |                      |
|                                    |                          |                      |



US3302384

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Was FSH sample collected?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                       |                          |                      |
|                       |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Collection date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Collection time](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:12 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 18:00:12 |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

**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 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |



US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

**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)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

**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)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

**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)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

**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)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

[Other](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                       |                          |                      |
|                       |                          |                      |



US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

[Specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

No Risk Identified

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

**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' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered 'I' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

[Other](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                  |                          |                      |
|                  |                          |                      |



US3302384

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:35

[Specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:00:34 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:46 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

Visit date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:46 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:46 |
|                                |                          |                      |
|                                |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:50:35**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 26 Aug 2020 18:32:46 |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

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

| Audit                      | User                                            | Time (GMT)           |
|----------------------------|-------------------------------------------------|----------------------|
| User entered '26 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Aug 2020 18:11:21 |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

What was the participant's randomization number?

| Audit                 | User                                            | Time (GMT)           |
|-----------------------|-------------------------------------------------|----------------------|
| User entered '108673' | RWS_ENDPOINT<br>ENDPOINT (b) (4)<br><div></div> | 26 Aug 2020 18:11:21 |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

[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 Aug 2020 18:11:21 |



US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

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)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:54 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:54 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

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

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:54 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

Diabetes (Type I, Type 2, or gestational)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:54 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

[Liver Disease](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:32:54 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'No (N)'                      | (b) (4), (b) (6) | 11 Nov 2020 18:09:17 |
|                                            |                  |                      |
| DataPoint set to visible.                  | System           | 23 Oct 2020 14:55:38 |
| Amendment Manager inserted this DataPoint. | System           | 19 Sep 2020 08:05:18 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:35

Height

| Audit                                                                                                                                                                                                                            | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)         | 08 Oct 2020 07:53:47 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'                             | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:23 |
| answered with 'done' (Site from DM).                                                                                                                                                                                             |                          |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                      | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)         | 30 Sep 2020 13:16:02 |
| User entered '61' in                                                                                                                                                                                                             | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:35

Weight

| Audit                                                                          | User                                   | Time (GMT)           |
|--------------------------------------------------------------------------------|----------------------------------------|----------------------|
| User entered missing code ND - Not Done; reason for<br>change Data Entry Error | Brittany Belcher (b) (4)<br>[REDACTED] | 07 Oct 2020 18:57:19 |
| User entered '150' lb                                                          | Brittany Belcher (b) (4)<br>[REDACTED] | 26 Aug 2020 19:47:42 |



US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:35

Height

| Audit                                                                                                                                                                                                                            | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)         | 08 Oct 2020 07:53:47 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'                             | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:23 |
| answered with 'done' (Site from DM).                                                                                                                                                                                             |                          |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                      | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)         | 30 Sep 2020 13:16:02 |
| User entered '61' in                                                                                                                                                                                                             | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:35

Weight

| Audit                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
|                                                                             |                          |                      |
| User entered '150' lb                                                       | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                                             |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Timepoint](#)

| Audit                                            | User                     | Time (GMT)           |
|--------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                  |                          |                      |
|                                                  |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Were vital signs assessed?](#)

| Audit                                                      | User                     | Time (GMT)           |
|------------------------------------------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
|                                                            |                          |                      |
| User entered 'No (N)'                                      | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                            |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User entered empty.                                            | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                    | User                     | Time (GMT)           |
|----------------------------------------------------------|--------------------------|----------------------|
| User entered '13:45' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User entered empty.                                      | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 13:45' | System | 07 Oct 2020 18:57:19 |
| User entered empty.              | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Temperature (xxx.x)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| User entered '97.7' F reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User entered empty.                                       | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |



US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Route of measurement](#)

| Audit                                                          | User                     | Time (GMT)           |
|----------------------------------------------------------------|--------------------------|----------------------|
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User entered empty.                                            | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Pulse \(xxx\)](#)

| Audit                                                 | User                     | Time (GMT)           |
|-------------------------------------------------------|--------------------------|----------------------|
| User entered '59' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
|                                                       |                          |                      |
| User entered empty.                                   | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                       |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'bpm'  | System | 07 Oct 2020 18:57:19 |
| User entered empty. | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                 | User                     | Time (GMT)           |
|-------------------------------------------------------|--------------------------|----------------------|
| User entered '14' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
|                                                       |                          |                      |
| User entered empty.                                   | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                       |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 07 Oct 2020 18:57:19 |
| User entered empty.        | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Systolic Blood Pressure (xxx)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| User entered '109' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User entered empty.                                    | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 07 Oct 2020 18:57:19 |
| User entered empty. | System | 26 Aug 2020 19:47:42 |



US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                 | User                     | Time (GMT)           |
|-------------------------------------------------------|--------------------------|----------------------|
| User entered '66' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
|                                                       |                          |                      |
| User entered empty.                                   | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                       |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 07 Oct 2020 18:57:19 |
| User entered empty. | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:35

Height

| Audit                                                                                                                                                                                                                            | User                     | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)         | 08 Oct 2020 07:53:47 |
| Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'                             | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:23 |
| answered with 'done' (Site from DM).                                                                                                                                                                                             |                          |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error                                                                                                                                                      | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
| User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6)         | 30 Sep 2020 13:16:02 |
| User entered '61' in                                                                                                                                                                                                             | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:35

Weight

| Audit                                                                       | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------|--------------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 07 Oct 2020 18:57:19 |
|                                                                             |                          |                      |
| User entered '150' lb                                                       | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                                             |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[Timepoint](#)

| Audit                                              | User                     | Time (GMT)           |
|----------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                                                    |                          |                      |
|                                                    |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Were vital signs assessed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                            |                          |                      |
|                            |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '14:53' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                      |                          |                      |
|                      |                          |                      |



**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 14:53' | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Temperature (xxx.x)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered '97.7' F | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'Oral (Oral)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[Pulse \(xxx\)](#)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '67' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '16' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 26 Aug 2020 19:47:42 |



US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Systolic Blood Pressure (xxx)

| Audit              | User                     | Time (GMT)           |
|--------------------|--------------------------|----------------------|
| User entered '116' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                    |                          |                      |
|                    |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Diastolic Blood Pressure (xxx)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '72' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:42 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 26 Aug 2020 19:47:42 |

US3302384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Was the physical examination performed?

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:46 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Date of examination (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:46 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

Was the pregnancy test performed?

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

Date of test (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                     |                          |                      |
|                     |                          |                      |



US3302384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Test performed](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Result](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Was FSH sample collected?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                       |                          |                      |
|                       |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Collection date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Collection time](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 19:47:52 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Aug 2020 19:47:52 |

US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

[Was study treatment given?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:33:09 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

If No, reason not given

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:33:09 |
|                     |                          |                      |
|                     |                          |                      |



US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:33:09 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:50:35**

[What was the study treatment?](#)

| Audit                               | User   | Time (GMT)           |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 26 Aug 2020 18:33:09 |

US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 18:33:09 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '14:23' | Brittany Belcher (b) (4) | 26 Aug 2020 18:33:09 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 14:23' | System | 26 Aug 2020 18:33:09 |

US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

Which arm was used to give treatment?

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:33:09 |
|                                    |                          |                      |
|                                    |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 26 Aug 2020 18:33:09 |

US3302384

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

What was the route of administration for the study treatment?

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 26 Aug 2020 18:33:09 |



US3302384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:02 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:02 |
|                            |                          |                      |
|                            |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:50:35**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:52' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:02 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 13:52' | System | 26 Aug 2020 19:48:02 |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '26 Aug 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:35

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |
|                                                              |                          |                      |
|                                                              |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:35

Collection time (00:00 - 23:59)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:50' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |
|                      |                          |                      |
|                      |                          |                      |



**US3302384**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 13:50' | System | 26 Aug 2020 19:48:14 |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:35

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |
|                                                              |                          |                      |
|                                                              |                          |                      |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                                                     | User                     | Time (GMT)           |
|-----------------------------------------------------------|--------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Wendy Taylor (b) (4)     | 20 Oct 2020 18:29:56 |
| User entered 'Yes (Y)'                                    | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |

US3302384

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:35

Collection time (00:00 - 23:59)

| Audit                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------|--------------------------|----------------------|
| User entered empty; reason for change Data Entry Error | Wendy Taylor (b) (4)     | 20 Oct 2020 18:29:56 |
|                                                        |                          |                      |
| User entered '13:50'                                   | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:14 |
|                                                        |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered empty.              | System | 20 Oct 2020 18:29:56 |
| User entered '26 Aug 2020 13:50' | System | 26 Aug 2020 19:48:14 |

US3302384

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 19:48:18 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 19:48:18 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:43:26', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'a843ab40-567f-4ae6-a6a5-56f4b7ed9386' | System | 26 Aug 2020 18:43:50 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 26 Aug 2020 18:43:50 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:43:33', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'a843ab40-567f-4ae6-a6a5-56f4b7ed9386' | System | 26 Aug 2020 18:43:50 |
| User entered '97.7'                                                                                                                                                                                                                                            | System | 26 Aug 2020 18:43:50 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:43:40', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'a843ab40-567f-4ae6-a6a5-56f4b7ed9386' | System | 26 Aug 2020 18:43:50 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 18:43:50 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:43:46', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'a843ab40-567f-4ae6-a6a5-56f4b7ed9386' | System | 26 Aug 2020 18:43:50 |
| User entered '26 Aug 2020 14:43'                                                                                                                                                                                                                               | System | 26 Aug 2020 18:43:50 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 14:43' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 17:13' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:16', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd461a71c-cf3c-47a8-b99c-f944696fdb8b' | System | 27 Aug 2020 12:18:27 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 27 Aug 2020 12:18:27 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:19', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd461a71c-cf3c-47a8-b99c-f944696fdb8b' | System | 27 Aug 2020 12:18:27 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 27 Aug 2020 12:18:27 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:22', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd461a71c-cf3c-47a8-b99c-f944696fdb8b' | System | 27 Aug 2020 12:18:27 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 12:18:27 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:25', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd461a71c-cf3c-47a8-b99c-f944696fdb8b' | System | 27 Aug 2020 12:18:27 |
| User entered '27 Aug 2020 08:18'                                                                                                                                                                                                                               | System | 27 Aug 2020 12:18:27 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 18:08' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 2' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:11', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd28ff442-0354-4605-8ae2-d9d0f87efb7e' | System | 28 Aug 2020 12:49:21 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 28 Aug 2020 12:49:21 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:14', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd28ff442-0354-4605-8ae2-d9d0f87efb7e' | System | 28 Aug 2020 12:49:21 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 28 Aug 2020 12:49:21 |



US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:17', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd28ff442-0354-4605-8ae2-d9d0f87efb7e' | System | 28 Aug 2020 12:49:21 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 12:49:21 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:19', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd28ff442-0354-4605-8ae2-d9d0f87efb7e' | System | 28 Aug 2020 12:49:21 |
| User entered '28 Aug 2020 08:49'                                                                                                                                                                                                                               | System | 28 Aug 2020 12:49:21 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 4' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:06', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '784c80f4-8152-4899-b65f-ca0cfb20b481' | System | 29 Aug 2020 16:07:24 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 29 Aug 2020 16:07:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:15', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '784c80f4-8152-4899-b65f-ca0cfb20b481' | System | 29 Aug 2020 16:07:24 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 29 Aug 2020 16:07:24 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:19', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '784c80f4-8152-4899-b65f-ca0cfb20b481' | System | 29 Aug 2020 16:07:24 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 29 Aug 2020 16:07:24 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:21', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '784c80f4-8152-4899-b65f-ca0cfb20b481' | System | 29 Aug 2020 16:07:24 |
| User entered '29 Aug 2020 12:07'                                                                                                                                                                                                                               | System | 29 Aug 2020 16:07:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 5' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:04', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9b11b5fc-c264-4d9f-ac7b-febef8766509' | System | 31 Aug 2020 12:51:17 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 31 Aug 2020 12:51:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

Please record your **TEMPERATURE** in °F

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:09', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9b11b5fc-c264-4d9f-ac7b-febef8766509' | System | 31 Aug 2020 12:51:17 |
| User entered '98.0'                                                                                                                                                                                                                                            | System | 31 Aug 2020 12:51:17 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:11', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9b11b5fc-c264-4d9f-ac7b-febef8766509' | System | 31 Aug 2020 12:51:17 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 31 Aug 2020 12:51:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:14', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9b11b5fc-c264-4d9f-ac7b-febef8766509' | System | 31 Aug 2020 12:51:17 |
| User entered '31 Aug 2020 08:51'                                                                                                                                                                                                                               | System | 31 Aug 2020 12:51:17 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 6' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:25', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '19460620-1444-45e6-8c41-9f57eecdcc30' | System | 01 Sep 2020 13:19:35 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 01 Sep 2020 13:19:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:28', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '19460620-1444-45e6-8c41-9f57eecdcc30' | System | 01 Sep 2020 13:19:35 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 01 Sep 2020 13:19:35 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:29', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '19460620-1444-45e6-8c41-9f57eecdcc30' | System | 01 Sep 2020 13:19:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Sep 2020 13:19:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:31', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '19460620-1444-45e6-8c41-9f57eecdcc30' | System | 01 Sep 2020 13:19:35 |
| User entered '01 Sep 2020 09:19'                                                                                                                                                                                                                               | System | 01 Sep 2020 13:19:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 7' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**Was TEMPERATURE taken?**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:03', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3b22a6ec-3b58-4c2e-8253-fc94825b6f00' | System | 02 Sep 2020 12:22:13 |
| User entered 'Yes (Y)'                                                                                                                                                                                                                                         | System | 02 Sep 2020 12:22:13 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

Please record your **TEMPERATURE in °F**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:07', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3b22a6ec-3b58-4c2e-8253-fc94825b6f00' | System | 02 Sep 2020 12:22:13 |
| User entered '98.4'                                                                                                                                                                                                                                            | System | 02 Sep 2020 12:22:13 |

US3302384

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:09', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3b22a6ec-3b58-4c2e-8253-fc94825b6f00' | System | 02 Sep 2020 12:22:13 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 12:22:13 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:11', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3b22a6ec-3b58-4c2e-8253-fc94825b6f00' | System | 02 Sep 2020 12:22:13 |
| User entered '02 Sep 2020 08:22'                                                                                                                                                                                                                               | System | 02 Sep 2020 12:22:13 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:43:54', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '395ca466-3655-450d-a6c5-5362e309059e' | System | 26 Aug 2020 18:44:31 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:44:31 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:12', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '395ca466-3655-450d-a6c5-5362e309059e' | System | 26 Aug 2020 18:44:31 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 18:44:31 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:19', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '395ca466-3655-450d-a6c5-5362e309059e' | System | 26 Aug 2020 18:44:31 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 18:44:31 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:26', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '395ca466-3655-450d-a6c5-5362e309059e' | System | 26 Aug 2020 18:44:31 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:44:31 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:28', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '395ca466-3655-450d-a6c5-5362e309059e' | System | 26 Aug 2020 18:44:31 |
| User entered '26 Aug 2020 14:44'                                                                                                                                                                                                                               | System | 26 Aug 2020 18:44:31 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 14:43' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 17:13' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:29', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f0870033-a457-4c08-bc66-0ca938342246' | System | 27 Aug 2020 12:18:43 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:18:43 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:32', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f0870033-a457-4c08-bc66-0ca938342246' | System | 27 Aug 2020 12:18:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 12:18:43 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:34', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f0870033-a457-4c08-bc66-0ca938342246' | System | 27 Aug 2020 12:18:43 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 12:18:43 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:36', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f0870033-a457-4c08-bc66-0ca938342246' | System | 27 Aug 2020 12:18:43 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:18:43 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:18:40', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f0870033-a457-4c08-bc66-0ca938342246' | System | 27 Aug 2020 12:18:43 |
| User entered '27 Aug 2020 08:18'                                                                                                                                                                                                                               | System | 27 Aug 2020 12:18:43 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 18:08' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 2' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:23', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7c5c4074-1a4c-4ff7-aec2-20a21e0d7983' | System | 28 Aug 2020 12:49:35 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:25', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7c5c4074-1a4c-4ff7-aec2-20a21e0d7983' | System | 28 Aug 2020 12:49:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 12:49:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:26', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7c5c4074-1a4c-4ff7-aec2-20a21e0d7983' | System | 28 Aug 2020 12:49:35 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 12:49:35 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:29', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7c5c4074-1a4c-4ff7-aec2-20a21e0d7983' | System | 28 Aug 2020 12:49:35 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:30', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7c5c4074-1a4c-4ff7-aec2-20a21e0d7983' | System | 28 Aug 2020 12:49:35 |
| User entered '28 Aug 2020 08:49'                                                                                                                                                                                                                               | System | 28 Aug 2020 12:49:35 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 4' | System | 26 Aug 2020 18:33:09 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:24', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '0e2f040e-d971-4c86-bc59-450a1da02b38' | System | 29 Aug 2020 16:07:33 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 29 Aug 2020 16:07:33 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:25', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '0e2f040e-d971-4c86-bc59-450a1da02b38' | System | 29 Aug 2020 16:07:33 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 29 Aug 2020 16:07:33 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:26', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '0e2f040e-d971-4c86-bc59-450a1da02b38' | System | 29 Aug 2020 16:07:33 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 29 Aug 2020 16:07:33 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:28', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '0e2f040e-d971-4c86-bc59-450a1da02b38' | System | 29 Aug 2020 16:07:33 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 29 Aug 2020 16:07:33 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:29', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '0e2f040e-d971-4c86-bc59-450a1da02b38' | System | 29 Aug 2020 16:07:33 |
| User entered '29 Aug 2020 12:07'                                                                                                                                                                                                                               | System | 29 Aug 2020 16:07:33 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 5' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:18', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '04f8e584-790d-4896-8912-b1302df07c03' | System | 31 Aug 2020 12:51:26 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:20', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '04f8e584-790d-4896-8912-b1302df07c03' | System | 31 Aug 2020 12:51:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 31 Aug 2020 12:51:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:21', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '04f8e584-790d-4896-8912-b1302df07c03' | System | 31 Aug 2020 12:51:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 31 Aug 2020 12:51:26 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:22', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '04f8e584-790d-4896-8912-b1302df07c03' | System | 31 Aug 2020 12:51:26 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:24', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '04f8e584-790d-4896-8912-b1302df07c03' | System | 31 Aug 2020 12:51:26 |
| User entered '31 Aug 2020 08:51'                                                                                                                                                                                                                               | System | 31 Aug 2020 12:51:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 6' | System | 26 Aug 2020 18:33:09 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:34', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd8033217-5164-461d-8c93-e75cd76964f2' | System | 01 Sep 2020 13:19:42 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:19:42 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:37', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd8033217-5164-461d-8c93-e75cd76964f2' | System | 01 Sep 2020 13:19:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Sep 2020 13:19:42 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:38', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd8033217-5164-461d-8c93-e75cd76964f2' | System | 01 Sep 2020 13:19:42 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Sep 2020 13:19:42 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:39', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd8033217-5164-461d-8c93-e75cd76964f2' | System | 01 Sep 2020 13:19:42 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:19:42 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:41', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd8033217-5164-461d-8c93-e75cd76964f2' | System | 01 Sep 2020 13:19:42 |
| User entered '01 Sep 2020 09:19'                                                                                                                                                                                                                               | System | 01 Sep 2020 13:19:42 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 7' | System | 26 Aug 2020 18:33:09 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:14', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f537f8d7-682f-42c1-9851-40ba47962b40' | System | 02 Sep 2020 12:22:26 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:22:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:17', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f537f8d7-682f-42c1-9851-40ba47962b40' | System | 02 Sep 2020 12:22:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 12:22:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:18', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f537f8d7-682f-42c1-9851-40ba47962b40' | System | 02 Sep 2020 12:22:26 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 12:22:26 |

US3302384

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:21', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f537f8d7-682f-42c1-9851-40ba47962b40' | System | 02 Sep 2020 12:22:26 |
| User entered 'None (1)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:22:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:23', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'f537f8d7-682f-42c1-9851-40ba47962b40' | System | 02 Sep 2020 12:22:26 |
| User entered '02 Sep 2020 08:22'                                                                                                                                                                                                                               | System | 02 Sep 2020 12:22:26 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                                                | User   | Time (GMT)           |
|----------------------------------------------------------------------|--------|----------------------|
| Data entry locked.                                                   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:38', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:45:11 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:41', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:45:11 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:45', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:45:11 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:49', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:45:11 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:52', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:45:11 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:44:56', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 26 Aug 2020 18:45:11 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:45:06', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' | System | 26 Aug 2020 18:45:11 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Aug 2020 18:45:11 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                                                           | User   | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-26T14:45:09', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9af8a2bd-a0a3-4ca3-829d-e1c4c02167ee' User entered '26 Aug 2020 14:45' | System | 26 Aug 2020 18:45:11 |
|                                                                                                                                                                                                                                                                                                 | System | 26 Aug 2020 18:45:11 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 14:43' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 17:13' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                             | User   | Time (GMT)           |
|---------------------------------------------------|--------|----------------------|
| Data entry locked.                                | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:04', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:19:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:07', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:19:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:09', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:19:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:11', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:19:24 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:13', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:19:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:14', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 27 Aug 2020 12:19:24 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:19', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 27 Aug 2020 12:19:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-27T08:19:21', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '853f714f-ae64-458b-a833-f5ca88540bde' | System | 27 Aug 2020 12:19:24 |
| User entered '27 Aug 2020 08:19'                                                                                                                                                                                                                               | System | 27 Aug 2020 12:19:24 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 18:08' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 2' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:34', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:58 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:38', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:58 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:39', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:58 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:45', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:58 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:46', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:58 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:48', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 28 Aug 2020 12:49:58 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:54', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 28 Aug 2020 12:49:58 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-28T08:49:56', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1c49d9b5-2d57-441d-a493-c95131def44d' | System | 28 Aug 2020 12:49:58 |
| User entered '28 Aug 2020 08:49'                                                                                                                                                                                                                               | System | 28 Aug 2020 12:49:58 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 4' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:32', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:33', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:35', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:36', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:38', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:39', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'None (0)'                                                                                                                                                                                                                                       | System | 29 Aug 2020 16:07:47 |



US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:41', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered 'No (N)'                                                                                                                                                                                                                                         | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-29T12:07:43', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '86becef1-a9a5-4750-bfb7-b0688be4fdb' | System | 29 Aug 2020 16:07:47 |
| User entered '29 Aug 2020 12:07'                                                                                                                                                                                                                              | System | 29 Aug 2020 16:07:47 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '29 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 5' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:27', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:28', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:29', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:39 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:30', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:31', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:33', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:34', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-08-31T08:51:36', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '919831a1-d0df-49b3-80c0-37e80f732a3c' | System | 31 Aug 2020 12:51:39 |
| User entered '31 Aug 2020 08:51'                                                                                                                                                                                                                               | System | 31 Aug 2020 12:51:39 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '30 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 6' | System | 26 Aug 2020 18:33:09 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:43', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:20:01 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:45', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:20:01 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:46', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:20:01 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:47', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:20:01 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:48', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:20:01 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:49', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 01 Sep 2020 13:20:01 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:51', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 01 Sep 2020 13:20:01 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-01T09:19:56', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '7800b314-b85c-4f8a-b83c-c5420019ea53' | System | 01 Sep 2020 13:20:01 |
| User entered '01 Sep 2020 09:19'                                                                                                                                                                                                                               | System | 01 Sep 2020 13:20:01 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '31 Aug 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 7' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**HEADACHE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:48', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'No interference with activity (1)'                                                                                                                                                                                                               | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**FATIGUE**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:22:52', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**MUSCLE ACHES ALL OVER BODY**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:23:02', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:23:04', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**NAUSEA/VOMITING**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:23:06', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:23:17 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

**CHILLS**

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:23:07', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 02 Sep 2020 12:23:17 |

US3302384

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:23:10', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-02T08:23:16', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '2ac6a2fc-1d5c-4484-886c-ea68b1ca0cec' | System | 02 Sep 2020 12:23:17 |
| User entered '02 Sep 2020 08:23'                                                                                                                                                                                                                               | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '01 Sep 2020 12:00' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '02 Sep 2020 11:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 12:23:17 |
| User entered 'Day 9' | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-04T08:17:06', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1d916a4f-627e-499f-8463-9b6ca38052cc' | System | 04 Sep 2020 12:17:12 |
| User entered 'None (0)'                                                                                                                                                                                                                                        | System | 04 Sep 2020 12:17:12 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time Stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-04T08:17:08', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '1d916a4f-627e-499f-8463-9b6ca38052cc' | System | 04 Sep 2020 12:17:12 |
| User entered '04 Sep 2020 08:17'                                                                                                                                                                                                                               | System | 04 Sep 2020 12:17:12 |



**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| Data entry locked.   | System | 02 Sep 2020 12:23:17 |
| User entered 'Day 9' | System | 02 Sep 2020 12:23:17 |

US3302384

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:50:35

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 (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-04T08:17:13', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9ab9955b-c683-4051-8c52-bfce76863388' | System | 04 Sep 2020 12:17:17 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 04 Sep 2020 12:17:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Time stamp](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B1BCC110-5126-4927-9495-D2875267F2D6)', Time: '2020-09-04T08:17:15', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '9ab9955b-c683-4051-8c52-bfce76863388' | System | 04 Sep 2020 12:17:17 |
| User entered '04 Sep 2020 08:17'                                                                                                                                                                                                                               | System | 04 Sep 2020 12:17:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 12:23:17 |

**US3302384**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:50:35**

[PC Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 12:23:17 |

US3302384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:11 |
|                        |                      |                      |
|                        |                      |                      |



US3302384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                    | User                                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------|
| User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 08 Oct 2020 17:44:07 |
| User entered '2 Sep 2020'                                                                                                                                                                                                                | Wendy Taylor (b) (4)<br>[REDACTED]<br>[REDACTED] | 09 Sep 2020 13:54:11 |

US3302384

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:11 |
|                                            |                      |                      |
|                                            |                      |                      |

**US3302384**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:11 |
|                     |                      |                      |
|                     |                      |                      |

US3302384

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:16 |
|                        |                      |                      |
|                        |                      |                      |

**US3302384**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Sep 2020 13:54:16 |

US3302384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:24 |
|                        |                      |                      |
|                        |                      |                      |

US3302384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                    | User                                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------|
| User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 08 Oct 2020 17:44:07 |
| User entered '9 Sep 2020'                                                                                                                                                                                                                | Wendy Taylor (b) (4)<br>[REDACTED]<br>[REDACTED] | 09 Sep 2020 13:54:24 |

US3302384

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:24 |
|                                            |                      |                      |
|                                            |                      |                      |



**US3302384**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:24 |
|                     |                      |                      |
|                     |                      |                      |

US3302384

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 09 Sep 2020 13:54:28 |
|                        |                      |                      |
|                        |                      |                      |

**US3302384**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Sep 2020 13:54:28 |

**US3302384**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 16 Sep 2020 14:58:55 |
|                        |                      |                      |
|                        |                      |                      |

US3302384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                    | User                                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------|
| User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 08 Oct 2020 17:44:07 |
| User entered '16 Sep 2020'                                                                                                                                                                                                               | Wendy Taylor (b) (4)<br>[REDACTED]<br>[REDACTED] | 16 Sep 2020 14:58:55 |

US3302384

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4) | 16 Sep 2020 14:58:55 |
|                                            |                      |                      |
|                                            |                      |                      |

**US3302384**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Wendy Taylor (b) (4) | 16 Sep 2020 14:58:55 |
|                     |                      |                      |
|                     |                      |                      |

US3302384

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 16 Sep 2020 14:58:58 |
|                        |                      |                      |
|                        |                      |                      |



**US3302384**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Sep 2020 14:58:58 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:23 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                   | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System). | System                   | 15 Oct 2020 14:47:18 |
| User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System). | System                   | 08 Oct 2020 17:44:07 |
| User entered '23 Sep 2020'                                                                                              | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:23 |
|                                                                                                                         |                          |                      |
|                                                                                                                         |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:23 |
|                                |                          |                      |
|                                |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:50:35**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 23 Sep 2020 18:40:23 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Timepoint](#)

| Audit                                            | User                     | Time (GMT)           |
|--------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                                                  |                          |                      |
|                                                  |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Were vital signs assessed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit                                                                                                                                                                                                                    | User                                                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------|
| User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                               | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                               | 08 Oct 2020 17:44:07 |
| User entered '23 Sep 2020'                                                                                                                                                                                               | Brittany Belcher (b) (4)<br>[REDACTED]<br>[REDACTED] | 23 Sep 2020 18:40:59 |



US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:30' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 13:30' | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Temperature (xxx.x)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered '98.4' F | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'Oral (Oral)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

[Pulse \(xxx\)](#)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '79' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

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

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '18' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                   |                          |                      |
|                   |                          |                      |



**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Systolic Blood Pressure (xxx)

| Audit              | User                     | Time (GMT)           |
|--------------------|--------------------------|----------------------|
| User entered '115' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                    |                          |                      |
|                    |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:35

Diastolic Blood Pressure (xxx)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '82' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[Timepoint](#)

| Audit                                              | User                     | Time (GMT)           |
|----------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                                                    |                          |                      |
|                                                    |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Were vital signs assessed?

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |



US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Temperature (xxx.x)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[Route of measurement](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

[Pulse \(xxx\)](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |



**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Systolic Blood Pressure (xxx)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:35

Diastolic Blood Pressure (xxx)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:40:59 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:40:59 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Was the physical examination performed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:06 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Date of examination (dd MMM yyyy)

| Audit                                                                                                                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System). | System                   | 15 Oct 2020 14:47:18 |
| User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System). | System                   | 08 Oct 2020 17:44:07 |
| User entered '23 Sep 2020'                                                                                                                                   | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:06 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

Was the pregnancy test performed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:16 |
|                        |                          |                      |
|                        |                          |                      |



US3302384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

Date of test (dd MMM yyyy)

| Audit                                                                                                                                                                                                              | User                                                 | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|----------------------|
| User closed query 'Date of Test is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                               | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Test is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                               | 08 Oct 2020 17:44:07 |
| User entered '23 Sep 2020'                                                                                                                                                                                         | Brittany Belcher (b) (4)<br>[REDACTED]<br>[REDACTED] | 23 Sep 2020 18:41:16 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Test performed](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User entered 'Urine (URINE)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:16 |
|                              |                          |                      |
|                              |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Result](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| User entered 'Negative (NEGATIVE)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:16 |
|                                    |                          |                      |
|                                    |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:35

[Was FSH sample collected?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:16 |
|                       |                          |                      |
|                       |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Collection date](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:16 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

[Collection time](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:16 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:41:16 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

[Was study treatment given?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:39:49 |
|                       |                          |                      |
|                       |                          |                      |



US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

If No, reason not given

| Audit                                                                                                                                                                               | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Per CDM: Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you' (Site from DM).                                               | (b) (4), (b) (6)         | 16 Oct 2020 20:00:12 |
| Query 'Per CDM: Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you' answered with 'per monitor this subject was asymptomatic' (Site from DM). | Wendy Taylor (b) (4)     | 15 Oct 2020 14:42:03 |
| User opened query 'Per CDM: Please complete applicable forms associated with confirmed COVID-19 diagnosis. Thank you' (Site from DM).                                               | (b) (4), (b) (6)         | 30 Sep 2020 15:09:49 |
| User entered 'Confirmed COVID-19 (COVID)'                                                                                                                                           | Brittany Belcher (b) (4) | 23 Sep 2020 18:39:49 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:39:49 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

[What was the study treatment?](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:39:49 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

What was the treatment date? (dd MMM yyyy)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:39:49 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:39:49 |
|                     |                          |                      |
|                     |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:39:49 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

Which arm was used to give treatment?

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 23 Sep 2020 18:39:49 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:35

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:39:49 |



**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Sep 2020 18:39:49 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:48 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

Collection date (dd MMM yyyy)

| Audit                                                                                                                                                  | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System). | System                   | 15 Oct 2020 14:47:18 |
| User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System). | System                   | 08 Oct 2020 17:44:07 |
| User entered '23 Sep 2020'                                                                                                                             | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:48 |
|                                                                                                                                                        |                          |                      |
|                                                                                                                                                        |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:50:35**

[Collection time \(00:00-23:59\)](#)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:42' | Brittany Belcher (b) (4) | 23 Sep 2020 18:41:48 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 13:42' | System | 23 Sep 2020 18:41:48 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:35

Collection date (dd MMM yyyy)

| Audit                                                                                                                                                                                                                 | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                   | 15 Oct 2020 14:47:18 |
| User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                   | 08 Oct 2020 17:44:07 |
| User entered '23 Sep 2020'                                                                                                                                                                                            | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                                                                                                                                                                                                                       |                          |                      |
|                                                                                                                                                                                                                       |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:35

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                                                              |                          |                      |
|                                                              |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                        |                          |                      |
|                        |                          |                      |



US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:35

Collection time (00:00 - 23:59)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:40' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 13:40' | System | 23 Sep 2020 18:42:04 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:35

[Lab Test](#)

| Audit                                                        | User                     | Time (GMT)           |
|--------------------------------------------------------------|--------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                                                              |                          |                      |
|                                                              |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:35

Collection time (00:00 - 23:59)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:40' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:04 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 13:40' | System | 23 Sep 2020 18:42:04 |

US3302384

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 23 Sep 2020 18:42:09 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Sep 2020 18:42:09 |



**US3302384**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 01 Oct 2020 15:52:53 |
|                        |                      |                      |
|                        |                      |                      |

US3302384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                    | User                                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------|
| User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 08 Oct 2020 17:44:07 |
| User entered '1 Oct 2020'                                                                                                                                                                                                                | Wendy Taylor (b) (4)<br>[REDACTED]<br>[REDACTED] | 01 Oct 2020 15:52:53 |

US3302384

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4) | 01 Oct 2020 15:52:53 |
|                                            |                      |                      |
|                                            |                      |                      |

**US3302384**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Wendy Taylor (b) (4) | 01 Oct 2020 15:52:53 |
|                     |                      |                      |
|                     |                      |                      |

US3302384

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 01 Oct 2020 15:52:46 |
|                        |                      |                      |
|                        |                      |                      |

**US3302384**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Oct 2020 15:52:46 |

US3302384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Was Contact Attempted?](#)

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 07 Oct 2020 17:30:02 |
|                        |                      |                      |
|                        |                      |                      |

US3302384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                    | User                                             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|----------------------|
| User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                                           | 08 Oct 2020 17:44:07 |
| User entered '7 Oct 2020'                                                                                                                                                                                                                | Wendy Taylor (b) (4)<br>[REDACTED]<br>[REDACTED] | 07 Oct 2020 17:30:02 |



US3302384

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--------------------------------------------|----------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Wendy Taylor (b) (4) | 07 Oct 2020 17:30:02 |
|                                            |                      |                      |
|                                            |                      |                      |

**US3302384**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                 | Time (GMT)           |
|---------------------|----------------------|----------------------|
| User entered empty. | Wendy Taylor (b) (4) | 07 Oct 2020 17:30:02 |
|                     |                      |                      |
|                     |                      |                      |

US3302384

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                 | Time (GMT)           |
|------------------------|----------------------|----------------------|
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 07 Oct 2020 17:30:06 |
|                        |                      |                      |
|                        |                      |                      |

**US3302384**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 07 Oct 2020 17:30:06 |

**US3302384**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 14:46:32 |

US3302384

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                                    | User             | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System           | 15 Oct 2020 14:47:18 |
| User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System           | 14 Oct 2020 14:46:32 |
| User entered '14 Oct 2020'                                                                                                                                                                                                               | (b) (4), (b) (6) | 14 Oct 2020 14:46:32 |

**US3302384**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--------------------------------------------|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Oct 2020 14:46:32 |

**US3302384**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 14:46:32 |



**US3302384**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 14:47:36 |

**US3302384**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Oct 2020 14:47:36 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

[Was this visit performed?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:09 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

Visit date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '20 Oct 2020' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:09 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:35

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:09 |
|                                |                          |                      |
|                                |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:50:35**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 20 Oct 2020 17:40:09 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Were vital signs assessed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '20 Oct 2020' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                            |                          |                      |
|                            |                          |                      |



**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:20' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Oct 2020 13:20' | System | 20 Oct 2020 17:40:37 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Temperature (xxx.x)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered '99.1' F | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'Oral (Oral)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

[If Other, specify](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

[Pulse \(xxx\)](#)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '84' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Oct 2020 17:40:37 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

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

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '16' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                   |                          |                      |
|                   |                          |                      |



**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Oct 2020 17:40:37 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Systolic Blood Pressure (xxx)

| Audit              | User                     | Time (GMT)           |
|--------------------|--------------------------|----------------------|
| User entered '113' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                    |                          |                      |
|                    |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Oct 2020 17:40:37 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:35

Diastolic Blood Pressure (xxx)

| Audit             | User                     | Time (GMT)           |
|-------------------|--------------------------|----------------------|
| User entered '78' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:37 |
|                   |                          |                      |
|                   |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:50:35**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Oct 2020 17:40:37 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Was the physical examination performed?

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:43 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:35

Date of examination (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '20 Oct 2020' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:43 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

[Was the sample collected?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:50 |
|                        |                          |                      |
|                        |                          |                      |



US3302384

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered '20 Oct 2020' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:50 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:35

Collection time (00:00-23:59)

| Audit                | User                     | Time (GMT)           |
|----------------------|--------------------------|----------------------|
| User entered '13:30' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:50 |
|                      |                          |                      |
|                      |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '20 Oct 2020 13:30' | System | 20 Oct 2020 17:40:50 |

US3302384

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 20 Oct 2020 17:40:53 |
|                        |                          |                      |
|                        |                          |                      |

**US3302384**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Oct 2020 17:40:53 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| DataPoint Activated.   | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated. | System | 08 Oct 2020 17:44:07 |
| Data entry locked.     | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 64'  | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-10-26T07:08:10', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd362827b-881b-42ba-b0c6-27110518c7eb' | System | 26 Oct 2020 11:08:19 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Oct 2020 11:08:19 |
| DataPoint Activated.                                                                                                                                                                                                                                           | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                         | System | 08 Oct 2020 17:44:07 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-10-26T07:08:11', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd362827b-881b-42ba-b0c6-27110518c7eb' | System | 26 Oct 2020 11:08:19 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 26 Oct 2020 11:08:19 |
| DataPoint Activated.                                                                                                                                                                                                                                           | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                         | System | 08 Oct 2020 17:44:07 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-10-26T07:08:15', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: 'd362827b-881b-42ba-b0c6-27110518c7eb' | System | 26 Oct 2020 11:08:19 |
| User entered '26 Oct 2020 07:08:15'                                                                                                                                                                                                                            | System | 26 Oct 2020 11:08:19 |
| DataPoint Activated.                                                                                                                                                                                                                                           | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                         | System | 08 Oct 2020 17:44:07 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| DataPoint Activated.             | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.           | System | 08 Oct 2020 17:44:07 |
| Data entry locked.               | System | 26 Aug 2020 18:33:09 |
| User entered '26 Oct 2020 00:01' | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| DataPoint Activated.             | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.           | System | 08 Oct 2020 17:44:07 |
| Data entry locked.               | System | 26 Aug 2020 18:33:09 |
| User entered '30 Oct 2020 23:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| DataPoint Activated.   | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated. | System | 08 Oct 2020 17:44:07 |
| Data entry locked.     | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 71'  | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-04T20:44:09', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '89c2e270-5138-4d10-aa46-64eba862590a' | System | 05 Nov 2020 01:44:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Nov 2020 01:44:40 |
| DataPoint Activated.                                                                                                                                                                                                                                           | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                         | System | 08 Oct 2020 17:44:07 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-04T20:44:31', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '89c2e270-5138-4d10-aa46-64eba862590a' | System | 05 Nov 2020 01:44:40 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 05 Nov 2020 01:44:40 |
| DataPoint Activated.                                                                                                                                                                                                                                           | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                         | System | 08 Oct 2020 17:44:07 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-04T20:44:34', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '89c2e270-5138-4d10-aa46-64eba862590a' | System | 05 Nov 2020 01:44:40 |
| User entered '04 Nov 2020 20:44:34'                                                                                                                                                                                                                            | System | 05 Nov 2020 01:44:40 |
| DataPoint Activated.                                                                                                                                                                                                                                           | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                         | System | 08 Oct 2020 17:44:07 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| DataPoint Activated.             | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.           | System | 08 Oct 2020 17:44:07 |
| Data entry locked.               | System | 26 Aug 2020 18:33:09 |
| User entered '02 Nov 2020 00:01' | System | 26 Aug 2020 18:33:09 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| DataPoint Activated.             | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.           | System | 08 Oct 2020 17:44:07 |
| Data entry locked.               | System | 26 Aug 2020 18:33:09 |
| User entered '06 Nov 2020 23:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                  | User   | Time (GMT)           |
|------------------------|--------|----------------------|
| DataPoint Activated.   | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated. | System | 08 Oct 2020 17:44:07 |
| Data entry locked.     | System | 26 Aug 2020 18:33:09 |
| User entered 'Day 78'  | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-09T06:34:20', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3553c36f-2408-4556-af0b-86eae12d017' | System | 09 Nov 2020 11:34:29 |
| User entered 'No (N)'                                                                                                                                                                                                                                         | System | 09 Nov 2020 11:34:29 |
| DataPoint Activated.                                                                                                                                                                                                                                          | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                        | System | 08 Oct 2020 17:44:07 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-09T06:34:24', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3553c36f-2408-4556-af0b-86eae12d017' | System | 09 Nov 2020 11:34:29 |
| User entered 'No (N)'                                                                                                                                                                                                                                         | System | 09 Nov 2020 11:34:29 |
| DataPoint Activated.                                                                                                                                                                                                                                          | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                        | System | 08 Oct 2020 17:44:07 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                         | User   | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-09T06:34:26', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '3553c36f-2408-4556-af0b-86eae12d017' | System | 09 Nov 2020 11:34:29 |
| User entered '09 Nov 2020 06:34:26'                                                                                                                                                                                                                           | System | 09 Nov 2020 11:34:29 |
| DataPoint Activated.                                                                                                                                                                                                                                          | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.                                                                                                                                                                                                                                        | System | 08 Oct 2020 17:44:07 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| DataPoint Activated.             | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.           | System | 08 Oct 2020 17:44:07 |
| Data entry locked.               | System | 26 Aug 2020 18:33:09 |
| User entered '09 Nov 2020 00:01' | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| DataPoint Activated.             | System | 15 Oct 2020 14:47:18 |
| DataPoint Inactivated.           | System | 08 Oct 2020 17:44:07 |
| Data entry locked.               | System | 26 Aug 2020 18:33:09 |
| User entered '13 Nov 2020 23:59' | System | 26 Aug 2020 18:33:09 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Oct 2020 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 Oct 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Oct 2020 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '03 Nov 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '06 Nov 2020 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '10 Nov 2020 23:59' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '13 Nov 2020 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '17 Nov 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                                                | User   | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-24T11:44:22', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '14527b16-b937-4a23-be76-0ab09cbd388f' User entered 'No (N)' | System | 24 Nov 2020 16:44:29 |
|                                                                                                                                                                                                                                                                                      | System | 24 Nov 2020 16:44:29 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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

| Audit                                                                                                                                                                                                                                                          | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-24T11:44:26', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '14527b16-b937-4a23-be76-0ab09cbd388f' | System | 24 Nov 2020 16:44:29 |
| User entered 'No (N)'                                                                                                                                                                                                                                          | System | 24 Nov 2020 16:44:29 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Date and time of submission](#)

| Audit                                                                                                                                                                                                                                                                                              | User   | Time (GMT)           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AEE8E5F6-61F4-4E53-9FD4-DFA0E7821C66)', Time: '2020-11-24T11:44:28', User OID: 'PatientReportedOutcome (US3302384)', ODM File OID: '14527b16-b937-4a23-be76-0ab09cbd388f' User entered '24 Nov 2020 11:44:28' | System | 24 Nov 2020 16:44:29 |

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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 18:20:55 |



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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 18:20:55 |



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

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 18:20:55 |

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 18:20:55 |

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

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 18:20:55 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 18:20:55 |

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

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[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 18:20:55 |

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**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

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**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

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**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 18:20:55 |



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 18:20:55 |



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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 18:20:55 |

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 18:20:55 |

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

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 18:20:55 |



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

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| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 18:20:55 |



**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Open Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 19 Nov 2020 18:20:55 |

**US3302384**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:50:35**

[Patient Cloud Close Date & Time](#)

| Audit                                               | User   | Time (GMT)           |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:20:55 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 19 Nov 2020 18:20:55 |



**US3302384**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Was Contact Attempted?](#)

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | brittany cooksey (b) (4)<br>(b) (4) | 18 Nov 2020 13:04:58 |

US3302384

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:35

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

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| User entered '18 Nov 2020' | brittany cooksey (b) (4)<br>(b) (4) | 18 Nov 2020 13:04:58 |

**US3302384**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--------------------------------------------|-------------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | brittany cooksey (b) (4)<br>(b) (4) | 18 Nov 2020 13:04:58 |

**US3302384**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:50:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| User entered empty. | brittany cooksey (b) (4)<br>(b) (4) | 18 Nov 2020 13:04:58 |

US3302384

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:35

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

| Audit                  | User                                | Time (GMT)           |
|------------------------|-------------------------------------|----------------------|
| User entered 'Yes (Y)' | brittany cooksey (b) (4)<br>(b) (4) | 18 Nov 2020 13:04:48 |

**US3302384**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:50:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 18 Nov 2020 13:04:48 |

US3302384

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

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

**Generated On: 26 Nov 2020 10:50:35**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:13 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                   | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 27 Aug 2020 17:59:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                               | Coder Import (b) (4)     | 27 Aug 2020 17:59:51 |
| Data point term sent to Coder                                                                                                                                                                           | System                   | 26 Aug 2020 18:12:49 |
| User entered 'lexapro'                                                                                                                                                                                  | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                                                                                                                                                                                                         |                          |                      |
|                                                                                                                                                                                                         |                          |                      |



US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

[Indication](#)

| Audit                             | User                     | Time (GMT)           |
|-----------------------------------|--------------------------|----------------------|
| User entered 'anxiety/depression' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                                   |                          |                      |
|                                   |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

[Dose per administration](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '5' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                  |                          |                      |
|                  |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

If dose unit is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                                |                          |                      |
|                                |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

If frequency is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                            |                          |                      |
|                            |                          |                      |



US3302384

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

Start date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'un May 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Start date completely unknown](#)

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Ongoing?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:12:47 |
|                       |                          |                      |
|                       |                          |                      |

**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 18:12:47 |

**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 18:12:47 |



**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:50:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 18:12:47 |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Name of Medication](#)

| Audit                                                                                                                                                                                                | User                     | Time (GMT)           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)     | 27 Aug 2020 17:59:56 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.                                                                                            | Coder Import (b) (4)     | 27 Aug 2020 17:59:56 |
| Data point term sent to Coder                                                                                                                                                                        | System                   | 26 Aug 2020 18:13:50 |
| User entered 'ativan'                                                                                                                                                                                | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                                                                                                                                                                                                      |                          |                      |
|                                                                                                                                                                                                      |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Prophylaxis](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Indication](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'anxiety' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Dose per administration](#)

| Audit              | User                     | Time (GMT)           |
|--------------------|--------------------------|----------------------|
| User entered '0.5' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                    |                          |                      |
|                    |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Dose unit](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

If dose unit is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                                |                          |                      |
|                                |                          |                      |



US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

If frequency is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:50:35**

If route of administration is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

Start date (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User entered 'un May 2020' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                            |                          |                      |
|                            |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

Start date completely unknown

| Audit            | User                     | Time (GMT)           |
|------------------|--------------------------|----------------------|
| User entered '0' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                  |                          |                      |
|                  |                          |                      |

**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Ongoing?](#)

| Audit                  | User                     | Time (GMT)           |
|------------------------|--------------------------|----------------------|
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                        |                          |                      |
|                        |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                     |                          |                      |
|                     |                          |                      |

US3302384

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:35

[Was this medication taken for solicited event?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:11 |
|                       |                          |                      |
|                       |                          |                      |



**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 18:13:11 |

**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Aug 2020 18:13:11 |

**US3302384**

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

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:50:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Aug 2020 18:13:11 |

US3302384

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:50:35**

[Were any concomitant procedures performed?](#)

| Audit                 | User                     | Time (GMT)           |
|-----------------------|--------------------------|----------------------|
| User entered 'No (N)' | Brittany Belcher (b) (4) | 26 Aug 2020 18:13:17 |
|                       |                          |                      |
|                       |                          |                      |

US3302384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:35

Date of dosing discontinuation (dd MMM yyyy)

| Audit                                                                                                                                                                           | User                     | Time (GMT)           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified.                                                                                                                                                             | (b) (4), (b) (6)         | 17 Nov 2020 21:22:53 |
| User closed query 'Please review source and revise if needed. Visit 1 dat was 26Aug2020, but results from Swab were not received until 02Sep2020.' (Site from CRA).             | (b) (4), (b) (6)         | 17 Nov 2020 21:22:49 |
| Query 'Please review source and revise if needed. Visit 1 dat was 26Aug2020, but results from Swab were not received until 02Sep2020.' answered with 'updated' (Site from CRA). | brittany cooksey (b) (4) | 17 Nov 2020 02:45:22 |
| User entered '02 Sep 2020' reason for change: Data Entry Error                                                                                                                  | (b) (4)                  | 17 Nov 2020 02:45:13 |
| User opened query 'Please review source and revise if needed. Visit 1 dat was 26Aug2020, but results from Swab were not received until 02Sep2020.' (Site from CRA).             | (b) (4), (b) (6)         | 21 Oct 2020 14:47:00 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                      | (b) (4), (b) (6)         | 20 Oct 2020 17:06:26 |
| User closed query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System).                                             | System                   | 15 Oct 2020 14:48:34 |
| User closed query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System).                                                       | System                   | 15 Oct 2020 14:48:34 |
| User entered '26 Aug 2020' reason for change: Data Entry Error                                                                                                                  | Wendy Taylor (b) (4)     | 15 Oct 2020 14:48:34 |
| User opened query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System).                                             | System                   | 15 Oct 2020 14:47:55 |
| User opened query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System).                                                       | System                   | 15 Oct 2020 14:47:55 |
| User entered '23 Aug 2020' reason for change: Data Entry Error                                                                                                                  | Wendy Taylor (b) (4)     | 15 Oct 2020 14:47:55 |
| Query 'Data is required. Please complete.' answered with 'will enter at end of study' (Site from System).                                                                       | Wendy Taylor (b) (4)     | 15 Oct 2020 14:44:52 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                      | System                   | 15 Oct 2020 14:44:32 |

US3302384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:35

Date of dosing discontinuation (dd MMM yyyy)

| Audit                                                                                                                                                                                                                                | User                     | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                   | 15 Oct 2020 14:44:32 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                               | Wendy Taylor (b) (4)     | 15 Oct 2020 14:44:32 |
| User opened query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                   | 15 Oct 2020 13:35:18 |
| User closed query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                   | 15 Oct 2020 13:35:18 |
| User entered '23 Sep 2020' reason for change: Data Entry Error                                                                                                                                                                       | Wendy Taylor (b) (4)     | 15 Oct 2020 13:35:18 |
| User opened query 'Date of dosing discontinuation is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System). | System                   | 08 Oct 2020 17:44:07 |
| User entered '01 Sep 2020'                                                                                                                                                                                                           | brittany cooksey (b) (4) | 03 Sep 2020 20:52:53 |

US3302384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:35

[Primary reason for dosing discontinuation](#)

| Audit                                                                                                                                                                                                                                                                                                                               | User                                | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User closed query 'Per CDM re-query: Thank you for your answer. However, Covid-19 Assessment should be completed. Please consider updating form or clarify otherwise. Thank you!' (Site from DM).                                                                                                                                   | (b) (4), (b) (6)                    | 24 Nov 2020 06:31:10 |
| Query 'Per CDM re-query: Thank you for your answer. However, Covid-19 Assessment should be completed. Please consider updating form or clarify otherwise. Thank you!' answered with 'what needs to be entered under the COVID 19 assessment form? Subject results came back positive for a normal scheduled visit.' (Site from DM). | brittany cooksey (b) (4)<br>(b) (4) | 23 Nov 2020 03:27:52 |
| User closed query 'For Query below, please just clarify in response to query. Covid 19 assessment page should only be completed if subject has symptoms and comes to the site for an Illness visit.' (Site from CRA).                                                                                                               | (b) (4), (b) (6)                    | 17 Nov 2020 21:23:28 |
| User opened query 'Per CDM re-query: Thank you for your answer. However, Covid-19 Assessment should be completed. Please consider updating form or clarify otherwise. Thank you!' (Site from DM).                                                                                                                                   | (b) (4), (b) (6)                    | 17 Nov 2020 06:56:55 |
| User closed query 'Per CDM-Response noted,however ,no data is updated on 'Covid -19 Assessment' form.Kindly consider to update else clarify.' (Site from DM).                                                                                                                                                                       | (b) (4), (b) (6)                    | 17 Nov 2020 06:56:55 |
| Query 'For Query below, please just clarify in response to query. Covid 19 assessment page should only be completed if subject has symptoms and comes to the site for an Illness visit.' answered with 'illness visit not completed' (Site from CRA).                                                                               | brittany cooksey (b) (4)<br>(b) (4) | 17 Nov 2020 02:46:31 |
| Query 'Per CDM-Response noted,however ,no data is updated on 'Covid -19 Assessment' form.Kindly consider to update else clarify.' answered with 'illness visit not completed' (Site from DM).                                                                                                                                       | brittany cooksey (b) (4)<br>(b) (4) | 17 Nov 2020 02:46:15 |
| User opened query 'For Query below, please just clarify in response to query. Covid 19 assessment page should only be completed if subject has symptoms and comes to the site for an Illness visit.' (Site from CRA).                                                                                                               | (b) (4), (b) (6)                    | 21 Oct 2020 19:19:30 |
| DataPoint Verified.                                                                                                                                                                                                                                                                                                                 | (b) (4), (b) (6)                    | 21 Oct 2020 14:55:08 |

US3302384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:35

[Primary reason for dosing discontinuation](#)

| Audit                                                                                                                                                                                                                                                                                                                                           | User                 | Time (GMT)           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|
| User opened query 'Per CDM-Response noted,however ,no data is updated on 'Covid -19 Assessment' form.Kindly consider to update else clarify.' (Site from DM).                                                                                                                                                                                   | (b) (4), (b) (6)     | 21 Oct 2020 07:13:23 |
| Query 'PerCDM Requery-Response noted,however, as per response,this patient wanted to remain in the study.Kindly confirm if patient is continuing the study,if yes,then please consider to remove all data entered in this form.Thank you. ' canceled (Site from DM).                                                                            | (b) (4), (b) (6)     | 21 Oct 2020 07:11:47 |
| User opened query 'PerCDM Requery-Response noted,however, as per response,this patient wanted to remain in the study.Kindly confirm if patient is continuing the study,if yes,then please consider to remove all data entered in this form.Thank you. ' (Site from DM).                                                                         | (b) (4), (b) (6)     | 21 Oct 2020 06:49:19 |
| User closed query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                                                                      | (b) (4), (b) (6)     | 20 Oct 2020 17:06:27 |
| User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation'form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM). | (b) (4), (b) (6)     | 16 Oct 2020 06:37:50 |
| User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error                                                                                                                                                                                                                                                                    | Wendy Taylor (b) (4) | 15 Oct 2020 14:47:55 |
| Query 'Data is required. Please complete.' answered with 'will enter at the end of study' (Site from System).                                                                                                                                                                                                                                   | Wendy Taylor (b) (4) | 15 Oct 2020 14:45:05 |
| User opened query 'Data is required. Please complete.' (Site from System).                                                                                                                                                                                                                                                                      | System               | 15 Oct 2020 14:44:32 |
| User entered empty; reason for change Data Entry Error                                                                                                                                                                                                                                                                                          | Wendy Taylor (b) (4) | 15 Oct 2020 14:44:32 |



US3302384

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:35

[Primary reason for dosing discontinuation](#)

| Audit                                                                                                                                                                                                                                                                                                                                                                                            | User                                | Time (GMT)           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'this patient wanted to remain in the study ' (Site from DM). | Wendy Taylor (b) (4)                | 15 Oct 2020 13:34:57 |
| User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'Covid -19 Assessment' form ,`Adverse event' form and 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).                                                 | (b) (4), (b) (6)                    | 10 Sep 2020 11:38:49 |
| Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However no data is recorded on 'Covid -19 Assessment ' form and 'end of study form' .Kindly verify and consider to update all the necessary eCRFs required else clarify.' canceled (Site from DM).                                                                                                  | (b) (4), (b) (6)                    | 10 Sep 2020 11:38:00 |
| User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However no data is recorded on 'Covid -19 Assessment ' form and 'end of study form' .Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).                                                                                               | (b) (4), (b) (6)                    | 10 Sep 2020 10:49:10 |
| User entered 'Due to SARS-COV-2 (COVID)'                                                                                                                                                                                                                                                                                                                                                         | brittany cooksey (b) (4)<br>(b) (4) | 03 Sep 2020 20:52:53 |

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Form: Dosing Discontinuation

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

| Audit               | User                                | Time (GMT)           |
|---------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)                    | 21 Oct 2020 14:55:11 |
| User entered empty. | brittany cooksey (b) (4)<br>(b) (4) | 03 Sep 2020 20:52:53 |

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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Date of study discontinuation/completion (dd MMM yyyy)

| Audit                                                                                           | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                      | (b) (4), (b) (6)         | 20 Oct 2020 17:07:00 |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Wendy Taylor (b) (4)     | 15 Oct 2020 14:47:30 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System                   | 15 Oct 2020 14:47:18 |
| User entered empty; reason for change Data Entry Error                                          | Wendy Taylor (b) (4)     | 15 Oct 2020 14:47:18 |
| User entered '26 Aug 2020'                                                                      | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |

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[Reason for discontinuation](#)

| Audit                                                                                           | User                     | Time (GMT)           |
|-------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System).                      | (b) (4), (b) (6)         | 20 Oct 2020 17:06:59 |
| Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System). | Wendy Taylor (b) (4)     | 15 Oct 2020 14:47:37 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System                   | 15 Oct 2020 14:47:18 |
| User entered empty; reason for change Data Entry Error                                          | Wendy Taylor (b) (4)     | 15 Oct 2020 14:47:18 |
| User closed query 'Data is required. Please complete.' (Site from System).                      | System                   | 08 Oct 2020 17:45:45 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).          | System                   | 08 Oct 2020 17:45:45 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error                                | Brittany Belcher (b) (4) | 08 Oct 2020 17:45:45 |
| User opened query 'Data is required. Please complete.' (Site from System).                      | System                   | 08 Oct 2020 17:44:07 |
| User entered empty.                                                                             | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:35

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

| Audit                                                                                                                                                                                                                             | User                     | Time (GMT)           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| User entered empty; reason for change Data Entry Error                                                                                                                                                                            | Wendy Taylor (b) (4)     | 15 Oct 2020 14:47:18 |
| User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). | System                   | 08 Oct 2020 17:45:53 |
| User entered 'Subject tested positive for Covid-19 at visit 1. Subject remains on study without receiving 2nd vaccine per protocol.' reason for change: Data Entry Error                                                          | Brittany Belcher (b) (4) | 08 Oct 2020 17:45:53 |
| User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). | System                   | 08 Oct 2020 17:45:45 |
| User entered empty.                                                                                                                                                                                                               | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |

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**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

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If reason for discontinuation is Death, main cause of death

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |
|                     |                          |                      |
|                     |                          |                      |

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If main cause of death is Other, specify

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |
|                     |                          |                      |
|                     |                          |                      |

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Date of death (*dd MMM yyyy*)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |
|                     |                          |                      |
|                     |                          |                      |



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[Was autopsy performed?](#)

| Audit               | User                     | Time (GMT)           |
|---------------------|--------------------------|----------------------|
| User entered empty. | Brittany Belcher (b) (4) | 08 Oct 2020 17:44:07 |
|                     |                          |                      |
|                     |                          |                      |